EXHIBIT 111

From: Randall, Mike [/o=BARD/ou=TPE AG/cn=Recipients/cn=MRandall]
To: Randall, Mike [Mike.Randall@crbard.com], Conaway, Jon [/o=BARD/ou=TPE AG/cn=Recipients/cn=jconaway], Baird, Bret [/o=BARD/ou=TPE AG/cn=Recipients/cn=BBaird], Chanduszko, Andre [/o=BARD/ou=TPE AG/cn=Recipients/cn=achanduszko], Garcia, JoseL [/o=BARD/ou=LPD AG/cn=Recipients/cn=JGarcia], Boyle, Brian [/o=BARD/ou=TPE AG/cn=Recipients/cn=BBoyle]
CC: Carr, Robert [/o=BARD/ou=TPE AG/cn=Recipients/cn=RCarr]
BCC: TPE-Saguaro [/o=BARD/ou=TPE AG/cn=Recipients/cn=TPE-Saguaro]
Subject: Platinum DIS discussion
Attachments: DIS-8049, rev.1.doc
Location: TPE-Saguaro
StartTime: 6/23/2008 6:00:00 PM
EndTime: 6/23/2008 7:00:00 PM
Timezone:

Hi All,

This meeting is to kick off the DIS for Platinum. The goal of this meeting is to determine what inputs we need to complete the DIS which will drive the project scope. Please think before hand how we can get the information we need to support the following:

1) EP
2) Stronger Snare Tip
3) Reduction of ID of sheath 1 French
4) Ergonomic changes to the delivery systems.
5) Color changes
6) Improved migration resistance
7) Improved tilt resistance
8) Reduction of penetrations
9) Anything else we want to consider for the project

Thanks

Mike

PS..Attached is a copy of the last DIS used for G3 which we can use as a outline.

McDermott
EXHIBIT NO. 7
2-5-14
Kim Thrall, CSR, RPR

Table of Contents

1.0 Purpose

This report documents and summarizes the design input information gathered during the concept phase of the G3 Vena Cava Filter project. This design input information is used to develop the Product Performance Specification (PPS), product design, and test plans. The business case for this project is outlined in Product Opportunity Appraisal POA-8049.

2.0 Scope

This design input summary applies to development of the G3 Vena Cava Filter. This report will document design input specific to the this product, as well as additional information related to actual use conditions and complaint data received on our currently marketed IVC Filters.

3.0 Information Sources

Design input information was gathered from multiple sources. These included the following:

- Discussions with clinicians who perform IVC Filter placement and retrieval procedures
- Focus group interviews with Interventional Radiologists, Trauma Surgeons, Bariatric Surgeons, Hematologists, Internal Medicine and Vascular Medicine specialists
- Market Research Studies
- Clinical Literature Review

- Complaint review
- MAUDE website review
- Regulatory requirements review

4.0 Project Background Information

BPV launched the Recovery Vena Cava Filter (RF-048F) with a permanent indication in April 2003, followed with the retrievable indication in October 2003. As the first IVC filter to receive a retrievable indication in the U.S., Recovery Filter brought a new level of awareness within the medical community to filter technologies and their associated complications.

Traditionally, permanent filters were placed primarily in patients with documented thromboembolic disease and a contraindication to or complication with anticoagulation. These patients typically received a filter during their hospital course and then were never follow up specifically for the filter. With newer, retrievable filters, not only are more patients receiving filters, but they are being followed at a higher rate due to the intent to retrieve the filter. The implication of this updated follow up regimen is that more asymptomatic filter complications are being discovered than ever before.

BPV discontinued the Recovery Filter in September 2005 and immediately replaced it with the G2 Filter (RF310F, RF210F), which has a permanent indication. As part of the routine passive post-market surveillance program, BPV began receiving reports of caudal migrations of the G2 Filter. Although the rate of caudal migration has always remained well below the reported rates in the SIR Quality Improvement Guidelines for IVC Filters, BPV undertook the effort to modify the design of the G2 Filter to improve its caudal migration resistance.

5.0 Summary of Design Input

Migration (both cranial and caudal) is a known and well-documented complication of vena caval filters. Although most agree that caudal migration is not the most serious of filter complications in terms of patient safety, it is nevertheless worrisome for most physicians when they encounter one of their patients with a filter that has migrated caudally.

Numerous sources and methods were utilized to determine the design input for this project. The main goal of the efforts was to determine the expected and threshold complication rates for IVC Filters. Below is a summary of the information gathered from each input source.

5.1 Literature Review

5.1.1 A comprehensive review of the available literature revealed that although caudal migration is not the most serious of possible filter complications, some filters in history have undergone redesign efforts (Titanium Greenfield) or were discontinued entirely (Gunther) due to caudal migration.

5.1.2 A secondary review of the available literature detailed the necessity of certain vena cava filter characteristics. These characteristics included (in no specific order):

- Self-Centering and Tilt Resistance
- No arm/leg entanglement (crossed limbs)
- Efficient clot trapping
- Caval patency
- Low profile
- Extended retrievability
- Easy retrieval
- Fracture resistance
- Migration resistance
- Filter sized accordingly (one sized filter fits most vena cava)
- Ability to power inject
- Accurate deployment
- Deployment with minimal force
- Perforation

The corresponding clinical literature is provided in Appendix G.

5.2 Market Research Studies

5.2.1 Bard Customer Surveys

A survey of Bard customers regarding their IVC Filter utilization was conducted in Q1 2005. Respondents were recruited by telephone and asked to fax back a 3-page questionnaire. A total of 154 surveys were completed and returned.

One of the questions in the survey assessed the problems that users have had with various types of optional filters. The responses showed a trend toward a higher (perceived) rate of migrations, perforations, and filter tilt with Bard's filter than the Gunther Tulip (Cook) or the OptEase (Cordis).

Q: Problems experienced with optional filters, by brand (n=154, multiple answers were accepted)

	Recovery (Bard)	Gunther Tulip (Cook)	OptEase (Cordis)
Filter tilt	38%	33%	3%
Inability to retrieve	24%	19%	11%
Filter migration	14%	3%	2%
Caval perforation	9%	3%	1%
Caval thrombosis	6%	11%	14%
Filter fracture	5%	3%	0%
Death	3%	1%	1%
Inadequate indwelling	1%	3%	3%
Other	5%	3%	5%

None	43%	55%	73%

5.2.2 Bariatric Surgeon Surveys

Another survey was completed in Q1 2005 involving Bariatric Surgeons and their filter utilization. The aim of this study was to assess bariatric surgeons' awareness of IVC Filter technology and the possible risks and benefits associated with caval interruption. Respondents were once again recruited by telephone and asked to fax back a 4-page questionnaire. A total of 90 completed surveys were returned.

One of the questions in this survey illustrated bariatric surgeons' general knowledge/perception of the types of complications that can occur with filters and how often:

Q: How often do you observe the following complications due to IVC Filters in your patients? (n=90)

	< 1% (Less than 1/1,000)	1% (1/100)	5% (5/100)	>5% (over 5/100)	Do Not See
Filter migration	41%	19%	4%	1%	34%
Caval Thrombosis	34%	20%	9%	1%	36%
Caval perforation	43%	9%	1%	0%	47%
Filter fracture	43%	6%	1%	0%	50%
Death	47%	6%	0%	0%	48%

The responses to the above question indicate that bariatric surgeons do and expect to see complications with filters. The majority expects to see these filter problems at a rate less than 1/1,000 cases.

5.3 Focus Groups

5.3.1 Multidisciplinary Panel

In June 2004, BPV convened a multidisciplinary panel of physicians with specific expertise and/or interest in thromboembolic disease and IVC Filters to discuss filter complications. This panel discussed many issues including expected and threshold rates for various filter complications and possible causes for these filter problems.

With regard to filter migration, the panel's perspective was the following.

- It should occur less than 1% of time
- For prophylactic filter placement, migration to the heart should virtually never happen. The rate should be less than 1 in 1,000.

- Migration should not be different for retrievable filters than for permanent filters.

It should be noted, however, that this discussion was mainly about proximal (or cranial) migration.
For caval perforations, the panel believed that symptomatic perforations should be less than 1% and that the rate of asymptomatic perforations does not matter.

In summary, the multidisciplinary panel felt the following about general filter performance:

- A retrievable filter is expected to perform just as well as a permanent filter.
- A filter should not migrate; no matter what the size of thrombus burden it captures.

5.3.2 Key Opinion Leader/High Volume User Panel

BPV convened another panel in June 2006 to discuss caudal migration of filters, specifically the BPV experience to date with the G2 Filter. This panel included Key Opinion Leaders and High-Volume users of IVC Filters. The list of panelists along with their profiles is included as Appendix D.

Below are some highlights of the discussion:

IVC Perforation:
- Could lead to erosion into duodenum, perforation of aorta, lodge in vertebral body
- OK if asymptomatic, but could become symptomatic over time
- 0 – 1% for "true" peforation; most perceived perfs are not "true" perforations
- Belief there is strong correlation between tilting and perforation

Migration (More than 2cm):
- Concern when goes to heart/lungs or goes from infrarenal vs suprarenal or symptomatic migration or in combination with tilt/perforation
- More concern over cephalad migration vs caudal migration
- Theoretical concern if filter migrates caudally, since there is more space above filter in the IVC for thrombus formation (source for recurrent PE)

BPV Experience:
- Should focus on symptomatic complications – asymptomatic events probably occur at a much higher rate because underreported
- At the time of the Expert Panel, there had been 3 symptomatic migrations in females: panelists thought these were coincidental in relation to small IVC diameter. Also, suggested females experience more abdominal & pelvic pain; therefore, may not be of real concern.
- The panelists expressed concern over 3 suprarenal caudal migrations vs 4

infrarenal that had been reported as of the date of the Panel. This does not represent actual placement practice: 100 infrarenals to 1 suprarenal.
- Generally, believe most migrations occur early (first 2 weeks) due to healing process
- Horizontal orientation: higher clot trapping efficiency may indicate higher risk of caval thrombosis and greater risk of pain due to stretching IVC
- Felt reassured by BPV's due diligence with clot trapping study
- Suggested IVC diameter may play role in caudal migration and tilting could lead to pain (symptomatic) in patients with smaller IVC due to stretching

Summary of Concerns Expressed:
- Inability to remove
- "True" migrations
- PE due to filter failure
- Concern with caudal rates but not in relation to other filters

Dr. Oliva Experience at CHUM:
- Of 40 attempted retrievals 24 anticoagulation contraindicated. 8 need prolonged filtration.
- 1 Caudal migration of 23 retrievals
- 17% tilting, some associated with perforation/penetration
- Retrieval window: 44 days (7 – 128)

Potential Root Causes for Caudal Migration:
- Believe most influential factor is caval dimensional changes
- Watermelon seed affect
- Small cava....more likely because arms may allow filter to ski down
- Large cava... arms more likely to catch and prevent downward migration
- Not much vessel spasm in IVC, but there is in small vessels

5.4 Field Visits

Numerous field visits were conducted by BPV sales, marketing, and R&D to respond to questions regarding various filter issues, including caudal migrations. These visits were also utilized to gather information regarding users' expected and threshold rates of various filter complications.

The main message that came out of the clinical interviews conducted during field visits is that users who have experienced caudal migrations of the G2 Filter are generally unhappy with the rate of this failure mode they are seeing. The users' perceived rate of caudal migrations seem to have a strong positive relationship with retrieval rate, as can be seen in the below table, which is a representative depiction of the general opinion based on utilization and retrieval rate.

Physician	Hospital	Annual Utilization	Retrieval Rate	Perceived caudal migration rate (G2 Filter)

Frank Lynch, MD	Hershey Penn State Hershey, PA	200 – 250 units	50%	30%
Mamood Razavi, MD	St. Joseph's Hospital Orange, CA	50 – 75 units	15%	1%
Bruce Zweibel, MD	Tampa General Hospital Tampa, FL	150 – 200 units	>5%	0%

Although most physicians believe that caudal migration has less serious patient safety implications than some other types of filter complications, they believe that a filter that moved caudally implies a general instability of the device in situ and therefore felt less comfortable using it as their default filter.

A summary of the field visit log, along with a justification of which of these design inputs will or will not be pursued as part of the G3 Filter project is located in Appendix F.

5.5 Complaint analysis

A thorough review of all received internal filter complaints was completed by conducting a search within Trackwise (BPV's internal complaint tracking software) by FDA code for both the currently marketed filter devices (Simon Nitinol Filter, G2 Filter, and Recovery Cone), as well as historically marketed filter devices (Recovery Filter). A detailed list of all complaints, shown by FDA code is shown in Appendix H. In summary, the top five complaints as of July 31, 2007 for each filter product are shown in the table below.

Filter Type	Top Five Reported Complaints				
	#1	#2	#3	#4	#5
SNF	Difficult to Deploy (QTY: 41)	Failure to Deploy (QTY: 26)	Twisting (QTY: 19)	Dome Collapse (QTY: 10)	Detachment of Components (QTY: 7)
Recovery	Detachment of Components (QTY: 123)	Migration* (QTY: 61)	Difficult to Deploy (QTY: 31)	Twisting (QTY: 31)	Perforation (QTY: 29)
G2 Femoral	Difficult to Deploy (QTY: 99)	Failure to Deploy (QTY: 73)	Migration** (QTY: 45)	Misplacement (QTY: 25)	Missing Components (QTY: 18)
G2 Jugular	Migration*** (QTY: 17)	Other**** (QTY: 7)	Broken Components (QTY: 5)	Twisting (QTY: 4)	Perforation (QTY: 4)
Recovery Cone	Detachment of Components (QTY: 26)	Broken Components (QTY: 7)	Bend (QTY: 4)	Failure to Capture (QTY: 4)	Other (QTY: 4)

*The majority of these migrations were in the cranial direction
**37 of these migrations were caudal, 8 were cranial
***All of these migrations were in the caudal direction
****Typically 'other' encompasses tilt and delayed opening

As well, a review of the MAUDE database was conducted, comparing the

complaint rates of all commercially available filters against the SIR Guidelines. It is important to keep in mind that companies are only liable for reporting medical device reports (MDRs) for those complaints that they determine could or have caused patient injury. Each company uses their own internal standards for making this determination, thus, there potentially exists a wide range of discrepancy from company to company on what complaints are reported to the FDA. A summary of the MAUDE database findings, as well as a ranking by company for each complaint type are provided in Appendix H.

5.6 Current Regulation Review

A review of the following regulations was completed:

- Guidance for Cardiovascular Intravascular Filter 510(k) Submissions, November 26, 1999
- Smith, Angela. Regulation of Peripheral Vascular Devices: Current issues in the regulation of IVC filters. Endovascular Today; Nov. 2005: 93-94
- Shelf Life of Medical Devices, April 1991
- Sterile, single-use intravascular catheters, ISO10555-1:1995
- Non-active surgical implants – General Requirements, ISO14630:1997
- Non-active surgical implants – Particular requirements for cardiac and vascular implants; Part 3: Endovascular devices, EN12006-3:1999

From this review, many additional regulatory requirements were identified, including, but not limited to: biocompatibility, simulated deployment, introducer/sheath suitability, clot trapping ability, filter fracture, caval perforation filter migration, thrombogenicity, MRI compatibility, and many more. The detailed requirements can be found in Appendix I.

Description of Change—

Revision number	Changes
000	Original/J.Hudnall
001	Updated project name from Tetra to G3 throughout, updated Appendix F to include rationale for user needs, changed document number from TD-00395 to DIS-8049/S.Klocke

Appendix A
Vena Cava Filter Usage Study Among Bard Customers Final Report

Appendix B
Vena Cava Filter Usage Study
Among Bariatric Surgeons
Final Report

Appendix C
Multidisciplinary Panel Summary Report

Appendix D
Key Opinion Leader/High-Volume User Panel Panelist Profile

Appendix E
Key Opinion Leader/High Volume User Panel Meeting Summary

Appendix F
Field Visit Log

Appendix G
Clinical Literature

Appendix H
Complaint Data

Appendix I
Regulatory Requirements

EXHIBIT 113

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN DIEGO, EAST COUNTY REGIONAL CENTER

- - -

MARY GIORDANO, individually and on Behalf of the Estate of Jacqueline Keith and other qualified survivors, Plaintiffs,	:	Case No. 37-2011-00069363-CU-PO-EC
vs.	:	
C.R. BARD, INC., a corporation, BARD PERIPHERAL VASCULAR INC., a corporation, THOMAS BRANNIGAN, M.D., an individual, FRANKLIN KALMAR, M.D., an individual, JULIE LAIDIG, M.D., an individual, SHARP GROSSMONT HOSPITAL, a corporation, SHARP HEALTHCARE, a corporation, and DOES 1 through 100 inclusive, Defendants.	:	

- - -

Tuesday, November 12, 2013

- - -

Videotaped Deposition of DAVID CIAVARELLA, M.D., held at Short Hills Hilton, 41 John F. Kennedy Parkway, Short Hills, New Jersey, on the above date, beginning at 9:43 a.m., before Kimberly A. Overwise, a Certified Realtime Reporter and Notary Public.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

BY MR. LOPEZ:

Q Well, are you aware that there was a -- do you keep up with the literature when it comes to things like that?

A I wouldn't say aggressively.

Q Okay. I'm going to -- I think if you look at the recent literature for this year, there's an article written in a peer-reviewed journal that has done research and has done an analysis of this so-called Webber effect, and the conclusion was there is no Webber effect. You haven't read that article?

A No.

Q Okay. And -- but, in any event, whether that article's valid or not valid or whether it trumps every other article that talks about Webber effect, the truth is in 2004 it was well known in -- at Bard and in the industry even when you were at J&J that you're only seeing the tip of the iceberg when you're dealing with voluntary reporting from clinicians when it comes to adverse events; right?

MS. DALY: Object to form.

THE WITNESS: I don't know if I'd call it the tip of the iceberg.

BY MR. LOPEZ:

Q Well, the tip of the ice -- what if it's -- what if you're right, it's 1 percent to 5 percent you're only getting?

A I don't know.

Q Okay. But there's a general consensus that that might be, in fact, the case, you're only getting 1 to 5 percent of what's actually happening, actually reported to the company or FDA?

A I mean, maybe yes, maybe no. That's the problem with it is you don't know.

Q But it --

A You could make an estimate, but an estimate's an estimate.

Q Right. But there was at one point in time -- I can show you the document later -- where you, Dr. Ciavarella, said one of the problems with reporting of events, voluntary reporting, is there's a consensus that you might be only getting 1 to 5 percent of the actual events; right?

A Could be. Yeah, there's a consensus.

Q So when -- in April -- I mean -- I'm sorry. Yeah, in April of 2004 when you're

Q No. I asked you based on the regulatory guideline -- regulatory protocol document that we marked earlier and the regulations that deal with adulterated products and misbranded products and recall, whether any of these rates now put us in a category where it's unacceptable, unexpected, unintended where recall should be considered?

MS. DALY: Object to the form.

THE WITNESS: I don't know because that's a decision made by Chris Ganser and his team and the quality assurance and the regulatory people. So I don't know how he applied it.

BY MR. LOPEZ:

Q And since you brought it up, I'm glad you agree with me that Dr. Grassi and the SIR don't control what are acceptable and unacceptable risks with respect to what should be warned about whether or not a product is properly designed or not designed or whether or not it should be recalled. You agree with me; right?

A I do.

Q And with respect to the Grassi

article, we're talking about the one in 2001?

A Yes.

Q And have you ever read the references to that article?

A I know I read some of them, but I can't recall if I've read all of them. It was some time ago.

Q And do you know what vintage of device those statistics are dealing with?

A Well, you know, the article was published that long ago, 2001. That was before the general category of retrievable filters was introduced in the marketplace. So it was largely the first and second generation of permanent filters probably.

Q You don't know?

A Well, I don't remember exactly. That's what I would guess.

Q Well, I mean, there are -- how many of the deaths that are referenced in the Grassi article are actually related to anything to do with a device malfunction?

A Yeah, I just don't remember. I think it would be a function of how transparent the article was that they were basing this, if they

Point -- Bullet Point 2, "Lack of thorough understanding dynamics of caval anatomy - impacting testing methods," what does that mean?

A Well, what it says, that understanding what happens to the vena cava during everyday activities and things is very poorly understood. So if we're trying to develop bench testing methods that would simulate an in vivo situation, it's very difficult to do that because we really don't have any good models or understanding of what happens to the cava.

Q Okay. This is the company's -- this is talking about the company itself has the lack of thorough understanding?

A Well, you can look --

Q Because the company can't speak --

A You can look at it as the company doesn't understand or you can look at it as nobody understands it. The thorough understanding of the dynamics of caval anatomy is something that's not well known -- not well understood.

Q Well -- well, okay. I mean, are you speaking from a position of having -- of authority meaning you've studied this, you've

EXHIBIT 116

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

* * * * * * * * * * * * * * *

In Re Bard IVC Filters Products Liability Litigation

No. MD-15-02641-PHX-DGC

* * * * * * * * * * * * * * *

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF TIMOTHY A. FISCHER

TAKEN AT: Quarles & Brady
LOCATED AT: 411 East Wisconsin Avenue
Milwaukee, WI

March 29, 2017
8:38 a.m. to 3:08 p.m.
REPORTED BY ANITA K. FOSS
REGISTERED PROFESSIONAL REPORTER

* * * * * * * * * * * * * * *

A. Yes.
Q. Where were you working?
A. E-Health Technologies.
Q. And what type of company is that?
A. Medical record retrieval company.
Q. What was your position?
A. Director of sales, and then vice president of sales and general manager of operations.
Q. Did you live in Rochester, New York at that time?
A. No, I lived where I live now.
Q. Did you have a sales territory?
A. I ran sales. I had salespeople reporting to me.
Q. And then where you worked before that was C.R. Bard; is that right?
A. Correct.
Q. According to your resumé, you worked there from 2000 to 2006?
A. Correct.
Q. What was your position?
A. Territory manager and then field sales manager.
Q. Tell me about your education background.

THE WITNESS: I'm not aware of that, no.
BY MR. O'CONNOR:
Q. And what you told us today is that you were a sales representative and you still are, and somebody that believed patient safety had to be first and foremost; right?
A. I was a sales representative, I believe. I'm not a sales representative anymore, but --
Q. All right. Thank you. But at the time though, you believed, and your goal was patient safety; right?
A. Yes.
Q. And that's why when we showed you a lot of these documents that you've never seen before today, the numbers you saw, the events you saw about the Recovery filter, were concerning to you; correct?
MR. LERNER: Objection to form.
THE WITNESS: Yeah, I think -- I think the -- the amount of documents with the numbers were -- were -- took me a little off guard, so to speak.
BY MR. O'CONNOR:
Q. And again, you were not provided that information by Bard back at the time that you were

addressing doctors and promoting Bard products; correct?

A. I don't believe I was, no.

Q. And this is the type of information that you wished you would have had, true?

A. I think if -- so I'm not going to lump the MAUDE database stuff in there, but I think if there is -- there is good clinical information that -- that was available, I would have wanted to present that to my physicians.

Q. Well, what you would do if you had a MAUDE database information that was verified by complaint files and other information, certainly that would help you understand the validity of the event recorded; right?

A. I would not have wanted to present any MAUDE database information to my physicians because it's not something that they hold as valuable.

Q. Different question. If Bard felt it was important enough to record that information and those events in weekly reports, that information was important enough to supply to you so you could have it knowing about your filter; right?

A. Yeah. So once they tracked it and did their announcements on it, if they thought it was

important, I would have wanted to have it, yes.

Q. And they didn't give it to you, did they?

A. They did not.

MR. O'CONNOR: Give me two minutes. I want to make sure I don't have anything else.

MR. LERNER: Okay.

THE VIDEOGRAPHER: Going off the record at 3:06.

(Break taken.)

THE VIDEOGRAPHER: We're back on the record at 3:08.

MR. O'CONNOR: All right. Mr. Fischer, I don't have any more questions. Thank you for your time today.

THE WITNESS: Thank you.

THE VIDEOGRAPHER: Going off the record at 3:08. Media four of four. End of deposition.

EXHIBIT 117

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

- - -

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	:	NO. MD-15-02641-PHX-DGC

- - -

July 18, 2017

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of MARK W. MORITZ, M.D., taken pursuant to notice, was held at the offices McCarter & English, LLP, 100 Mulberry Street, Newark, New Jersey, beginning at 9:07 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Q. Failures of Bard filters include tilting?
A. Correct.
Q. Failure of Bard filters include fracture?
A. Yes.
Q. Embolization?
A. Yes.
Q. And failures also include penetration into other organs, correct?
A. Correct.
Q. And you have seen at least in reviewing the plaintiff experts that there were internal documents in Bard which spoke to serious injuries, and even death caused by failure modes of Bard filters?
A. Correct.
Q. And certainly that's something I think you would agree that a medical doctor would want to know from a medical device company in making decisions about which type of devices to use for patients, fair?

MR. BROWN: Object to the form.

THE WITNESS: Yes.

BY MR. O'CONNOR:

Q. And certainly from what you've told me before, you certainly cannot discuss what if anything Bard did by way of warning of its knowledge of the types of filters and complications that Bard became aware of, true?

A. Well, I remember a letter around 2005 that I think I got.

Q. All right. So you got some kind of "Dear Colleague" or "Dear Doctor" letter?

A. "Dear Doctor" letter.

Q. You're not going to be talking about that letter in this trial, fair?

MR. BROWN: Object to the form.

THE WITNESS: No, I didn't intend to.

EXHIBIT 118

G2® Filter System

Timeless Performance®

G2® Filter System

Femoral Vein Approach

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The *G2®* Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the *G2®* Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the *G2®* Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing.

The *G2®* Filter is designed to act as a permanent filter. When clinically indicated, the *G2®* Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The *G2®* Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRI Safety:

Non-clinical testing has demonstrated that the *G2®* Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less;
2. Spatial gradient field of 450 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the *G2®* Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner.

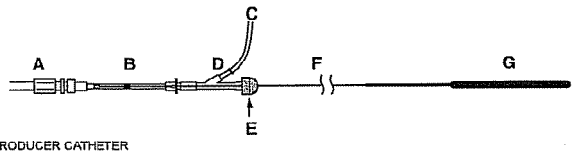
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the *G2®* Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

B. Device Description

The *G2®* Filter System - Femoral consists of the filter and delivery system. The *G2®* Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The *G2®* Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The *G2®* Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the *G2®* Filter, a storage tube with saline infusion port, and a pusher system. The *G2®* Filter is packaged pre-loaded within the delivery storage tube.

Figure A. *G2®* Filter System - Femoral



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the *G2®* Filter

C. Indications for Use

The *G2®* Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- *G2®* Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

D. Contraindications for Use

The *G2®* Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

***G2®* Filter Implantation**

1. The *G2®* Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2®* Filter cannot be safely reloaded into the storage tube.
2. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)
3. Delivery of the *G2®* Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.
4. The *G2®* Filter System - Femoral is designed for femoral approaches only. Never use the *G2®* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *G2®* Filter orientation within the IVC.
5. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.
6. Only use the *Recovery Cone®* Removal System to remove the *G2®* Filter. Never re-deploy a removed filter.
7. Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.
8. Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
9. Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
10. Persons with allergic reactions to nickel may suffer an allergic response to this implant.
11. After use, the *G2®* Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

See Potential Complications section for further information regarding other known filter complications.

***G2®* Filter Removal**

1. Do not attempt to remove the *G2®* Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena cava wall.

   NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. Use only the Bard *Recovery Cone®* Removal System (packaged separately) to retrieve the *G2®* Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.
3. Never re-deploy a removed filter.

F. Precautions

***G2®* Filter Implantation**

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the *G2®* Filter using a *Recovery Cone®* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
11. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
12. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
13. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

***G2®* Filter Removal**

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone®* Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the *G2®* Filter with the *Recovery Cone®* Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. Remove the *G2®* Filter using the *Recovery® Cone* Removal System Only. (Reference Optional Procedure for Filter Removal for specific removal instructions).
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion.
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter Tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood Loss
- Guidewire entrapment
- Pain

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One *G2®* filter and Delivery System that contains:
  - One 48cm, 7 French I.D. introducer catheter and dilator set
  - One Storage tube with pre-loaded *G2®* Filter and pusher delivery system
- 0.038" 3mm J-tipped Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: Scalpel, #11 blade, local anesthesia, drapes, etc

If the physician chooses to percutaneously remove the *G2®* Filter, the *Recovery Cone®* Removal System is available from C.R. Bard, Inc.

I. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

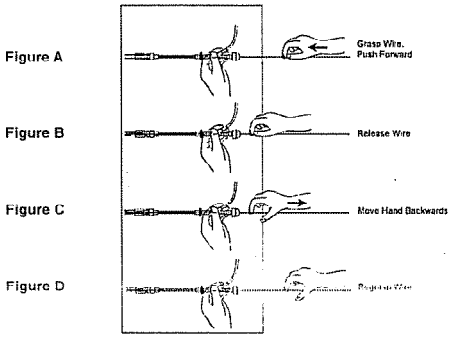
Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

11. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
12. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.

Advancement of G2® Filter, Illustrated



13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

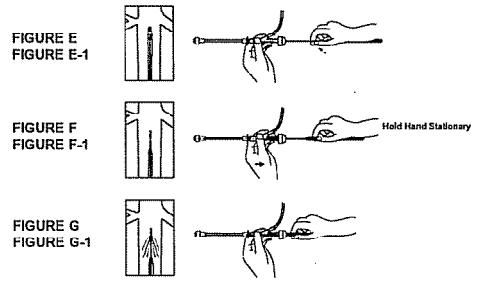
Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tub assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

15. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Vencavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30mL of contrast medium at 15mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the *G2®* Filter using the *Recovery Cone®* only.

Removal of *G2®* Filter

Equipment Required

The following equipment is required for use:

- One *Recovery Cone®* Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with *Recovery Cone®* and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium

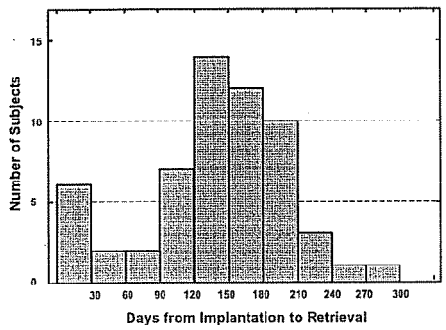
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the ***G2®*** Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time to retrieval.

Figure H: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the ***Recovery Cone®*** Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone®*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the **G2®** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the **G2®** Filter.

Recovery Cone® **Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone®*** Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

G2® Filter Removal, Illustrated

17. The capture of the G2® Filter is illustrated in Figures A-E:

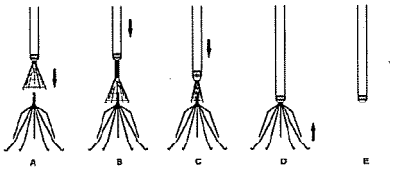


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the G2® Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the G2® Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 17.

J. How Supplied

Each ***G2®*** Filter is supplied preloaded in a storage tube. Each ***G2®*** Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Warning: After use, the G2® Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The ***G2®*** Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684]**
- **"American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hagspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.


G2® Filter System

Femoral

Femoral Introducer Catheter


Use By

Lot Number

REF Catalog Number


Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide

Non-pyrogenic

Single Use.

Do Not Resterilize.


Do Not Use If Package Is Damaged Or Opened.

MR Conditional

Contents: Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System


Protect From Heat


Keep Dry


Recommended Guidewire


Manufacturer:

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EXHIBIT 119

G2™ FILTER SYSTEM

for Permanent Placement

Timeless Performance

G2 Filter System
Femoral Vein Approach

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The **G2** Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the **G2** Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The femoral set is designed to advance through an 45 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the **G2** Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing.

The **G2** Filter is designed to act as a permanent filter.

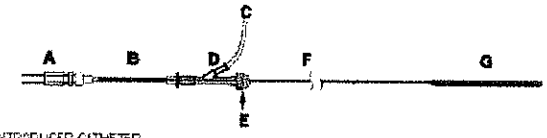
MRI Compatible. The **G2** Filter implant is MR-safe and neither interferes with nor is affected by the operations of a MRI device. The **G2** Filter performance was evaluated in a standard 1.5-Tesla MRI system.

B. Device Description

The **G2** Filter System - Femoral consists of the filter and delivery system. The **G2** Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The **G2** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The **G2** Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the **G2** Filter, a storage tube with saline infusion port, and a pusher system. The **G2** Filter is packaged pre-loaded within the delivery sheath/tube.

Figure A. G2 Filter System - Femoral



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the **G2** Filter.

C. Indications for Use

The **G2** Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy for thromboembolic disease
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The G2 Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

G2 Filter Implantation

1. **The G2 Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the G2 Filter cannot be safely reloaded into the storage tube.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)**
3. **Delivery of the G2 Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.**
4. **The G2 Filter System - Femoral is designed for femoral approaches only. Never use the G2 Filter and Delivery System for superior approaches (jugular, subclavian or anticubital vein), as this will result in improper G2 Filter orientation within the IVC.**
5. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.**
6. **Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.**
7. **Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.**
8. **Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.**
9. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
10. **After use, the G2 Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

See Potential Complications section for further information regarding other known filter complications.

F. Precautions

The safety and effectiveness of the G2 Filter System for use as a retrievable or temporary filter have not been established.

G2 Filter Implantation

1. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.
2. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
3. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast which do not clearly show the wall of the IVC may be misleading.
4. When measuring caval dimensions, consider an angiographic catheter or intravascular Ultrasound (IVUS) if there is any question about caval morphology.
5. Spinal deformities: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations.
6. In patients with contraindication of chronic, recurrent pulmonary embolism, patients should be returned to anticoagulation therapy as soon as it is deemed safe.
7. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and direct vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
8. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" section between which the filter should be positioned just prior to unsheathing and deployment.
9. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
10. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become coated by clot. This will interfere with filter deployment.
11. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Perforation or other acute or chronic damage to the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if the emboli passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram
- Air embolism
- Hematoma or nerve injury at the puncture site
- Hemorrhage
- Restriction of blood flow
- Occlusion of small vessels
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site

AE of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One **G2** Filter and Delivery System that contains:
  - One 45 cm, 7 French I.D. introducer catheter and dilator set
  - One storage tube with pre-loaded **G2** Filter and pusher delivery system
- 0.035" 3 mm Jagged Guidewire, 115 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

I. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access site, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of various thromboses.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open kit. A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

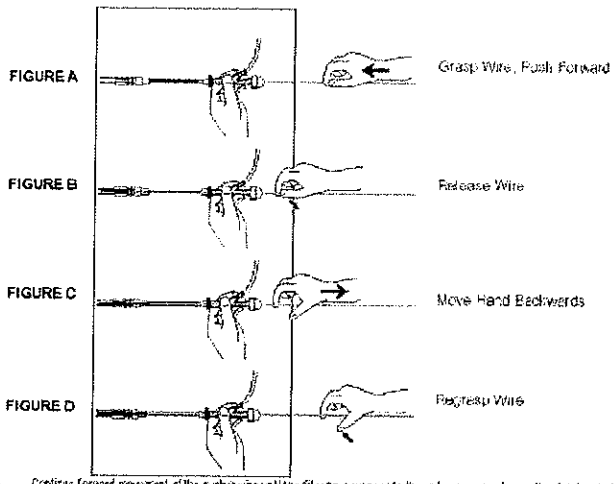
Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be left inside to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

11. Attach the blue end of the filter storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
12. Advance the filter by moving the inner pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the inner pusher wire may be looped, without causing kinking to the inner material, to facilitate pusher wire handling and advancement.

Advancement of Filter, Illustrated



13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

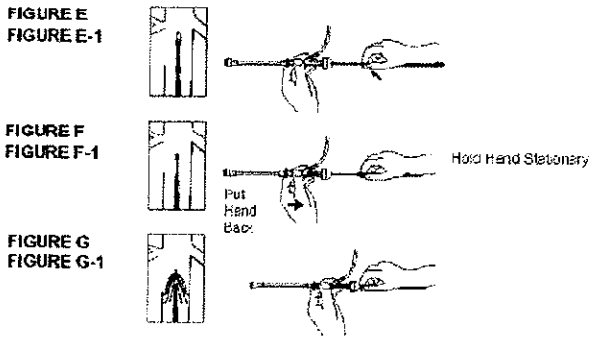
Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

15. Now withdraw the pusher wire back into the storage tube by fully folding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

J. How Supplied

Each G2 Filter is supplied preloaded in a storage tube. Each G2 Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sheathe or reload it.

Warning: After use, the G2 Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The G2 Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and solely under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

Labeling Issue Date: 11/06. In the event 2 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available.

References:

1. Quality Improvement Guidelines for Percutaneous Placement and Management of Inferior Vena Cava Filters. Grassi, Swan, Cardella, et al. J Vasc Interv Radiol 2003; 14:S271-S275.

G2 Filter System for Permanent Placement

Use By

Lot Number

Catalog Number

Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide

Non-pyrogenic

Single Use

Do Not Resterilize

Do Not Use If Package Is Damaged Or Opened

MRI compatible: MRI-safe and neither interferes with nor is affected by the operations of an MRI device.

Contents: Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System

Protect From Heat

Keep Dry

Manufactured By:

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G2 is a trademark of C. R. Bard, Inc. or an affiliate.

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PK5100030 Rev. 5 10/06

G2® Filter System

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G2® Filter System

ENGLISH

Femoral Vein Approach

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The G2® Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the G2® Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the G2® Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing.

The G2® Filter is designed to act as a permanent filter. When clinically indicated, the G2® Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2® Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRI Safety:

Non-clinical testing has demonstrated that the G2® Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less;
2. Spatial gradient field of 4,50 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the G2® Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner.

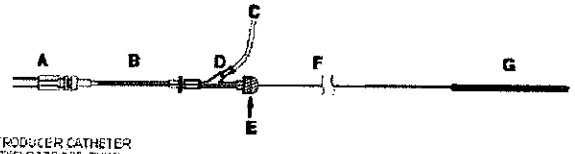
MR image quality may be compromised if the area of interest is in the exact same area or relatively near to the position of the G2® Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

B. Device Description

The G2® Filter System - Femoral consists of the filter and delivery system. The G2® Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The G2® Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The G2® Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the G2® Filter, a storage tube with saline infusion port, and a pusher system. The G2® Filter is packaged pre-loaded within the delivery storage tube.

Figure A. G2® Filter System - Femoral



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY/BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the G2® Filter.

C. Indications for Use

The G2® Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2® Filter may be removed according to the instructions supplied under Section labeled Optional Procedure for Filter Removal.

D. Contraindications for Use

The G2® Filter should not be implanted in:

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm
- Patients with risk of septic embolism

E. Warnings

G2® Filter Implantation

1. **The G2® Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the G2® Filter cannot be safely reloaded into the storage tube.**
2. **This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contract with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.**
3. **Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing, and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.**
4. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 6.)**
5. **Delivery of the G2® Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.**
6. **The G2® Filter System - Femoral is designed for femoral approaches only. Never use the G2® Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2® Filter orientation within the IVC.**
7. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.**
8. **Only use the *Recovery Cone*® Removal System to remove the G2® Filter. Never re-deploy a removed filter.**
9. **Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.**
10. **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**
11. **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.**
12. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
13. **After use, the G2® Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

See Potential Complications section for further information regarding other known filter complications.

G2® Filter Removal

1. **Do not attempt to remove the G2® Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena cava wall.**
   NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. **Use only the Bard *Recovery Cone*® Removal System (packaged separately) to retrieve the G2® Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.**
3. **Never re-deploy a removed filter.**

F. Precautions

G2® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. The safety and effectiveness of this device has not been established for pregnancy, nor in the suprarenal placement position.[1]
3. The safety and effectiveness of this device has not been established for morbidly obese patients. Open abdominal procedures such as bariatric surgery may affect the integrity and stability of the filter.
4. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
5. Procedures or activities that lead to changes in intra-abdominal pressure could affect the integrity or stability of the filter.
6. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
7. When measuring caval dimensions, consider an angiographic catheter or intravascular Ultrasound (IVUS) if there is any question about cava morphology.
8. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the G2® Filter using a *Recovery Cone*® Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
9. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
10. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
11. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
12. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
13. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly but without excessive force that may cause breakage of the hub.
14. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
15. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

G2® Filter Removal

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone*® Removal System. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

2. Spinal deformations: It is important to exercise care when contemplating removal the ***G2®*** Filter with the ***Recovery Cone®*** Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. Remove the ***G2®*** Filter using the ***Recovery® Cone*** Removal System Only. (Reference Optional Procedure for Filter Removal for specific removal instructions)
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device.

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or disengagement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site
- Hemorrhage
- Restriction of blood flow
- Occlusion of small vessels
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter Tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood Loss
- Guidewire entrapment
- Pain

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One ***G2®*** filter and Delivery System that contains:
  - One 40cm, 7 French I.D. introducer catheter and dilator set
  - One Storage tube with pre-loaded ***G2®*** Filter and pusher delivery system
- 0.035" 3mm J-tipped Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture. Scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to percutaneously remove the ***G2®*** Filter, the ***Recovery Cone®*** Removal System is available from C.R. Bard, Inc.

I. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open IVA Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter/obturator with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

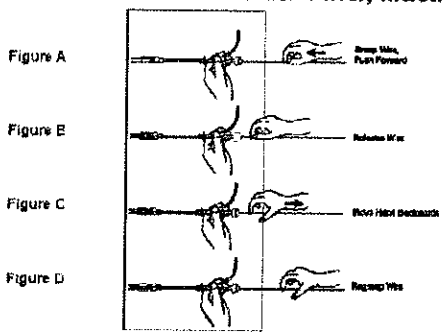
Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram in both the AP and lateral view, (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic guidance. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

11. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
12. Advance the filter by moving the inner pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the inner pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.

Advancement of G2® Filter, Illustrated



13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

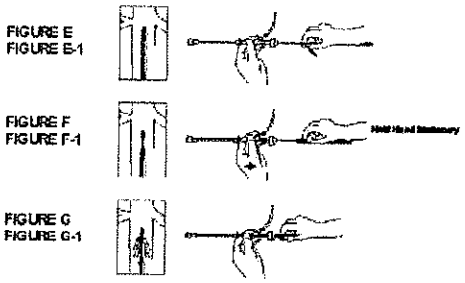
Filter Release/Deployment

14. Deliver and release filter as described below.

Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tub assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

15. Under fluoroscopic guidance, withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30mL of contrast medium at 15mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2® Filter using the *Recovery Cone®* only.

Removal of *G2®* Filter

Equipment Required

The following equipment is required for use:

- One ***Recovery Cone®*** Removal System that contains:
  - One 75 cm, 10 French I.D. introducer catheter and dilator set

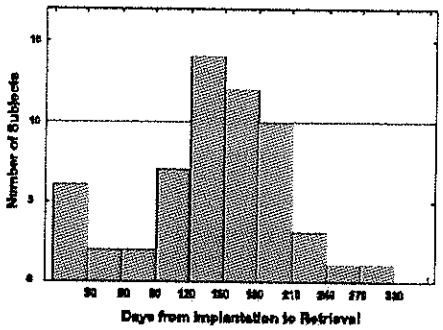
- One Y-adapter with **Recovery Cone®** and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the **G2®** Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved: 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-61.0. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time to retrieval.

Figure H: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the **Recovery Cone®** Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=3), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the **Recovery Cone®** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the **G2®** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the **G2®** Filter.

***Recovery Cone®* Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone®*** Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Until ready to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

G2® Filter Removal, Illustrated

NOTE: It is recommended to fluoroscopically obtain image(s) of the filter in AP and lateral views during the retrieval procedure.

17. The capture of the **G2®** Filter is illustrated in **Figures A-E**.

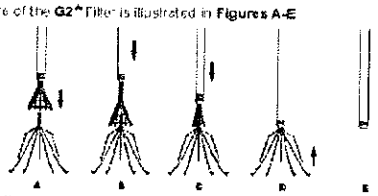


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the **G2®** Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the **G2®** Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (straight or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter bear the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 17.

J. How Supplied

Each **G2®** Filter is supplied preloaded in a storage tube. Each **G2®** Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to resterilize or reload it.

Warning: After use, the *G2®* Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The **G2®** Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of the booklet. In the event 36 months have elapsed between the date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684]**
- **"American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al. . J Vasc Interv Radiol 2003; 14:S27 -S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M. Radiology 2002, 225(3), 855-864.
3. Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days. Binkert, C., et al. J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al. J Vasc Interv Radiol 2005, 16(9), 1189-1195.
5. Difficult Retrieval of a Recovery IVC Filter. Tagspiel, K., et al. . J Vasc Interv Radiol 2004, 15(6) 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J. Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al. . J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al. Annals of Vascular Surgery 2006, 20(1) 157-165.

G2® Filter System

Femoral

Femoral Introducer Catheter

Use By

LOT Lot Number

REF Catalog Number

Attention, See Instructions for Use

STERILE EO Sterilized By Using Ethylene Oxide

NON PYROGENIC Non-pyrogenic

Single Use, Do Not Reuse

Do Not Resterilize.

Do Not Use if Package Is Damaged Or Opened.

MR Conditional

Contents: Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System

Protect From Heat

Keep Dry

Recommended Guidewire

Manufacturer:

Manufacturer:
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA

TEL 1-480-894-9515
1-800-321-4254
FAX: 1-480-858-7062
1-800-440-5376
www.bardpv.com

BARD PERIPHERAL VASCULAR

PK5250500 Rev. 2 10/09

Exhibit H-G

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

– – –

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC

- - -

OCTOBER 11, 2016

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER

CONFIDENTIALITY REVIEW

Videotaped deposition of CHRISTOPHER D. GANSER, held at HILTON SHORT HILLS, 41 John F. Kennedy Parkway, Short Hills, New Jersey, commencing at 9:32 a.m., before Margaret M. Reihl, a Registered Professional Reporter, Certified Realtime Reporter, and Notary Public.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Q. And it knew that it had an undesirable risk profile based on its own R002 that Dr. -- from Dr. Ciavarella's February 2006 HHE?

MS. DALY: Object to form.

BY MR. LOPEZ:

Q. Undesirable?

A. It was rated undesirable per the remedial action plan process.

Q. Yeah, and it was obviously rated as something that needed to be redesigned to deal with that -- those undesirable complications, true?

A. It needed to be addressed.

Q. Well, it needed to be redesigned, right?

MS. DALY: Object to the form.

BY MR. LOPEZ:

Q. There were some defects in the design of the G2 that was leading to the problems described in Dr. Civarella's February 2006 HHE; don't you agree, sir?

A. There were issues with the design that needed to be addressed.

MS. DALY: Ramon, can I interrupt you just a moment. I did not realize this, and you did not realize this, but the stipulation about

Exhibit H-H

IN THE UNITED STATES DISTRICT COURT
IN THE SOUTHERN DISTRICT OF FLORIDA

SAMANTHA BOULDRY, ELUA HUFF, SANDRA LORENZ, and JANET ROBERTS, on behalf of themselves and the class of all others similarly situated,	
Plaintiffs,	Case No: 12-80951-CIV-ROSENBAUM
vs.	
C. R. BARD, INC., a corporation of the State of New Jersey, and BARD PERIPHERAL VASCULAR, INC., a corporation of the State of Arizona, et al.,	
Defendants.	

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

DEPOSITION OF ROBERT MICHAEL CARR, JR.

Phoenix, Arizona
April 17, 2013

BY: KARLA M. MARTIN, RPR, CSR
Arizona CR No. 50485

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

identify a customer need with respect to tracking?

A. To enable more filters to be removed, yes.

Q. Okay. And explain how it is that tracking would enable the removal of more filters.

A. I don't know in particular in these cases. But oftentimes patients are lost to follow-up. They just move out of the system; or practices are busy, and they don't have the wherewithal to manage each and every patient, reminder phone call or whatever it may be.

Q. Before we move further down this road, with respect to the Recovery filter, it is a -- and let me get it right -- it is or was designed to act as a permanent filter, but when clinically indicated may be percutaneously removed after implantation according to the instructions provided under the removal procedures; is that correct?

A. Absolutely.

Q. All right. So it's first a permanent device that may be removed; is that correct?

A. Yes.

Q. All right. And that is true for the G2, as well as the G2 Express. Am I correct?

A. Yes.

Q. Do you know whether this customer issue or need went anywhere; that is, was there a tracking program that

A. No. It's empty.
Q. What is in the database?
A. Empty cells and address blocks and places for people to enter their information.
Q. Okay. Did Bard send out an informational letter, a Dear Doctor letter, anything of that nature, informing other physicians or hospitals about the existence of this database?
A. I don't know.
Q. What was the purpose of the database from your perspective?
MR. BORANIAN: I object to the form.
A. For Dr. Lynch to keep track of his patients.
Q. Was the database provided to any other physicians other than Dr. Lynch or other hospitals, for example?
A. Dr. Lynch created the database for himself. As I said, we provided the software to those who wanted it.
Q. But was the database shared with anyone other than Dr. Lynch?
A. It wasn't shared with anyone. No data was shared.
Q. All right. It was for Dr. Lynch's use only?
A. Yes.
Q. And to your knowledge, the existence of this database was not made known to other physicians or

Q. And how would this anchoring system reduce tilting of the filter?

A. If the filter can't move, it can't tilt.

Q. All right. And was the clinical data indicating that filters, the G2 and the G2 Express, were being placed, they were centered properly, but at some point there was an indication that some of these filters were tilting within the vena cava?

A. Whether they were placed tilted or centered, yes, there were reports of tilt post placement.

Q. But my question is a little more specific than that. It relates to those patients that were implanted with a filter, the filter was centrally placed in the vena cava.

A. Yes.

Q. Was there clinical data indicating that the G2 and the G2 Express were subsequently tilting after placement?

A. Yes.

Q. All right. And what's the significance when a filter tilts within the vena cava?

A. Usually nothing. But sometimes it can make it not retrievable. And as I alluded to before, it can cause it to penetrate or lead to a penetration.

Q. What about fracture?

A. Changing the stresses on the filter changes the stresses applied. So it could lead to fracture.

Q. All right. And this tilting phenomenon, if the G2 and/or the G2 Express were centrally placed, this tilting is, based on what I am reading here, related to the anchoring system, as opposed to individual patient factors. Agreed?

A. No. It's related to both.

Q. What were the -- what are the individual patient factors?

A. As I alluded to before, Valsalva, quad coughs, clot, increases in blood volume, surgery. There's all kinds of things that can affect or cause tilt.

Q. There's all sorts of potential hypothetical situations that can cause tilt. But what from Bard's standpoint was the realistic, day-to-day concern that was causing tilt to occur?

A. All of those things that I mentioned are the day-to-day concerns of what causes tilt; and therefore, our solution was, if we could stop the filter from being able to move or be tilted, then that's what we would do.

Q. So the thought was by changing the anchor system Bard could prevent the filter from tilting, if there's a cough by the patient, if there's a Valsalva maneuver, if the patient has changes in blood volume, if there is clot

that forms at or around the filter. Am I correct?

A. Reduce the number.

Q. All right. So Bard was of the view that if we change the anchoring system, these known or these thought-to-be causes for tilt would be reduced?

A. Yes.

Q. Feel free to review the entirety of Exhibit 7. When this document references the causes for tilt and fracture and penetration, let me know where in this document it mentions any individual patient characteristics that may potentially be causing these problems.

A. It wouldn't, but nor would it be expected to.

Q. Well, the reality is the IFU doesn't say if a patient coughs too much or if there's a Valsalva maneuver that these complications increase, does it?

A. The DFMEA does, which is the proper place to identify those risks and mitigations.

Q. What is the DFMA (sic)?

A. The DFMEA is the design failure modes and effects analysis.

Q. Who does Bard share that with?

A. The FDA.

Q. Is it provided to the physicians who are implanting these devices?

Exhibit H-J

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF MARICOPA

TINA BARKLEY and JEFFERY BARKLEY,
individually and as husband and wife,
Plaintiffs,
v. No. CV2011-021250
C.R. BARD, INC, et al.,
Defendants.

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

KEVIN PHILLIPS,

Plaintiff,

vs. Civil Action No.:
3:12-cv-00344-RCJ-WGC
C.R. BARD, INC., et al.,

Defendants.

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

MELANIE RACKLIFF, an individual,
Plaintiff,
v. NO. CV2011-021206
C.R. BARD, INC., et al.,
Defendants.

Deposition of DONNA BEATRICE TILLMAN, Ph.D.

more consistently reported for one device versus another. There is just a lot of variability.

Q. All right. That was a rude answer, because you didn't answer my question.

MR. ROGERS: Object. Ramon, stop trying to argue and harass the witness, please.

MR. LOPEZ: That was a rude answer because I didn't ask her that. That's being rude.

MR. ROGERS: Well, I don't appreciate you speaking to the witness that way.

MR. LOPEZ: All right. Well, I don't appreciate the witness continuously ducking questions.

MR. ROGERS: The witness is not ducking questions. The witness is answering your questions.

Q. The question is simple, are you aware of any evidence to suggest that physicians are more likely to report the same or similar adverse event of a particular medical device's -- to a particular medical device company over some

other company?

A. I am aware, and I can't -- I'm not going to be able to put my finger on it, of studies that have been done that show that medical device reporting can be subject to a host of inaccuracies, which include different device types, and may include -- you know, I don't think it would include companies, but there are reasons why that. So that's the best I can answer your question.

Q. Okay. Let me ask this question: Are you aware of any data that would suggest in any way that physicians are more likely to report embolization deaths of an inferior vena cava to one manufacturer over another manufacturer?

A. I am not aware of any data like that.

Q. Wouldn't you agree, ma'am, just having been in this world for as long as you've been in the pharmaceutical medical device regulatory world, that if a device causes a death or is associated with a death in some fashion that a physician is as likely to report it, in any event, regardless of who the manufacturer is?

Exhibit J-G

G2 X
VENA CAVA FILTER

Femoral Vein Approach
Instructions for Use

BARD PERIPHERAL VASCULAR

ENGLISH

Instructions for Use
For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The ***G2® X*** Filter is a venous interruption device designed to prevent pulmonary embolism. The unique design and material of the ***G2® X*** Filter provide filtering efficiency and allow percutaneous placement through a 7 French I.D. introducer sheath with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The ***G2® X*** Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The Femoral system allows for placement of the ***G2® X*** Filter via a femoral vein approach. The femoral delivery system consists of a dilator and introducer set and a delivery device. The dilator accepts a 0.038" guidewire and allows for an 900 psi maximum pressure contrast power injection. The 48cm, 7 French I.D. introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast via a syringe. The flexible nitinol pusher wire of the delivery device has a pad at the end of the wire designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the radiopaque distal end of the introducer sheath, positioned 1 cm below the lowest renal vein. The introducer sheath and delivery device are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the ***G2® X*** Filter to be deployed with the retrieval hook centered and minimizes the potential for legs crossing.

The ***G2® X*** Filter is designed to act as a permanent filter. When clinically indicated, the ***G2® X*** Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The ***G2® X*** Filter's anchors allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions).

MRI Safety:

The ***G2® X*** Vena Cava Filter was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the ***G2® X*** Vena Cava Filter is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

-Static magnetic field of 3-Tesla or less
-Spatial gradient magnetic field of 720-Gauss/cm or less
-Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the ***G2® X*** Vena Cava Filter produced a temperature rise of 0.8°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3-W/kg for 15-minutes of MR scanning in a 3-Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the ***G2® X*** Vena Cava Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

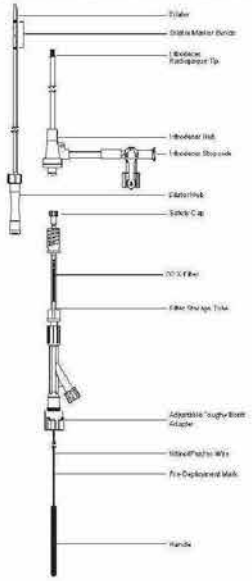
B. Device Description

The ***G2® X*** Vena Cava Filter System - Femoral consists of the filter and delivery system. The ***G2® X*** Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach.

The ***G2® X*** Filter consists of twelve shape-memory nitinol wires emanating from a central nitinol sleeve with a retrieval hook at the apex of the filter. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration.

The ***G2® X*** Vena Cava Filter System - Femoral is illustrated in Figure 1. The delivery system consists of a 7 French I.D. introducer sheath and dilator, the ***G2® X*** Filter, a storage tube with saline infusion port, and a pusher system. The ***G2® X*** Filter is packaged pre-loaded within the delivery storage tube.

Figure 1: *G2® X* Vena Cava Filter System – Femoral



IMPORTANT: Read instructions carefully before using the *G2® X* Filter

C. Indications for Use

The ***G2® X*** Vena Cava Filter - Femoral Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The ***G2® X*** Filter System – Femoral Delivery Kit is also indicated for use in patients with temporary increased risk of pulmonary embolism requiring caval interruption.

The ***G2® X*** Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The ***G2® X*** Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

G2® X **Filter Implantation**

1. **The *G2® X* Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2® X* Filter cannot be safely reloaded into the storage tube.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to PRECAUTION # 4.)**
3. **Delivery of the *G2® X* Filter through the introducer sheath is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer sheath.**
4. **The *G2® X* Vena Cava Filter - Femoral is designed for femoral approaches only. Never use the *G2® X* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *G2® X* Filter orientation within the IVC.**
5. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer sheath.**
6. **Never re-deploy a removed filter.**
7. **When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.**
8. **Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.**
9. **Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.**
10. **Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.**
11. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
12. **After use, the *G2® X* Vena Cava Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

See Potential Complications section for further information regarding other known filter complications.

G2® X **Filter Removal**

1. **Do not attempt to remove the *G2® X* Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.**

NOTE: It is possible that complications such as those described in the "Warnings, PRECAUTIONS, and Potential Complications" section of these Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

2. **Never re-deploy a removed filter.**
3. **Remove the *G2® X* Filter using an intravascular snare or the *Recovery Cone*® Removal System only. Refer to the Optional Procedure for Filter Removal section for details.**

F. PRECAUTIONS

G2® X **Filter Implantation**

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the retrieval hook 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement or sub-optimal placement of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the ***G2® X*** Filter using an intravascular snare or a ***Recovery Cone***® Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. The introducer sheath has a radiopaque distal tip to assist in visualization and predeployment filter positioning. The radioopaque distal tip on the introducer sheath, when used in conjunction with the radiopacity of the pusher wire spline, provides a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
11. Do not attempt to attach a syringe or power injection line to the proximal end of the introducer sheath hub. Injections should only be performed through the sidearm port.
12. Care should be taken to ensure the connection between the introducer sheath hub and the filter storage tube is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.
13. It is very important to maintain introducer sheath patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
14. Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer sheath. Do not twist the pusher wire handle at anytime during this procedure.

G2® X **Filter Removal**

1. Anatomical variances may complicate the removal procedure. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the ***G2® X*** Filter in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. When using the ***Recovery Cone***® Removal System, the cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement or migration of the filter and/or embolization of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs has also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One ***G2*** ***X*** Filter Femoral System that contains:
  - One 48 cm, 7 French I.D. introducer sheath and dilator set
  - One storage tube with pre-loaded ***G2*** ***X*** Filter and pusher delivery system
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

I. Directions for Use

Insertion of the 7 French Introducer Sheath and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the carton and outer pouch. Open the introducer sheath and dilator inner pouch.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

PRECAUTION: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the 18G entry needle over the J-tipped guidewire. Obtain the dilator and the introducer sheath from the package. Flush the dilator and the introducer with saline. Insert the dilator through the introducer sheath ensuring that the hubs connect properly. Advance the 7 French introducer sheath together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

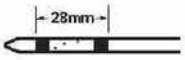
NOTE: A 0.038" guidewire is used to guide the dilator/introducer assembly beyond the implant site to ensure proper advancement.

PRECAUTION: It is very important to maintain introducer patency with a saline flush to prevent occlusion of the introducer, which may interfere with delivery device advancement.

7. Remove the guidewire and perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15mL/s) through the dilator. Check for caval thrombi, position of renal veins, and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).

NOTE: IVC diameter may be measured using dilator radiopaque marker bands. Marker bands are spaced at a distance of 28mm (outer-to-outer), which references the maximum indicated IVC diameter (Reference Figure 2).

Figure 2



WARNING: When injecting contrast medium through the dilator, do not exceed the maximum pressure rating of 800 psi.

WARNING: If the vena cava diameter is greater than 28mm, do not deploy the *G2* *X* Filter. If large thrombus is present at the initial delivery site, do not attempt to deliver the filter. Migration of the clot and/or filter may occur. Select an alternate site to deliver the filter. A small thrombus could be bypassed by the guidewire and introducer sheath.

8. Remove the dilator, leaving the introducer sheath with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer sheath a constant saline drip infusion to maintain introducer sheath patency.
9. Advance the introducer sheath to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer sheath tip should be 1 cm below the lowest renal vein.
10. Open the delivery system inner pouch. Remove the delivery system containing the filter from the package and remove the red safety cap (Reference Figure 3).

Figure 3: Safety Cap Removal

11. Flush the delivery system with saline through the Y-adapter.

PRECAUTION: It is very important to maintain introducer sheath patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer sheath already in the vein. The introducer sheath and filter delivery system should be held in a straight line to minimize friction.

PRECAUTION: Care should be taken to ensure the connection between the introducer sheath hub and the filter storage tube is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

13. Loosen the Tuohy-Borst and advance the filter by smoothly pushing the pusher wire forward through the introducer sheath (Reference Figure 4 A-D). Do not pull back on the pusher wire, only advance the pusher wire forward.

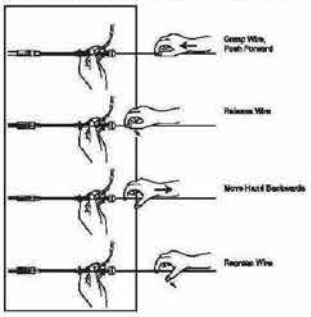
Figure 4 A-D: Advancement of Filter, Illustrated

FIGURE 4 A

FIGURE 4 B

FIGURE 4 C

FIGURE 4 D



14. Continue forward movement of the pusher wire until the filter retrieval hook advances to the radiopaque distal tip of the introducer sheath. At this point, the black mark on the pusher wire handle should be adjacent to the Y-adapter.

Filter Release/Deployment

15. Deliver and release filter as described in Figure 5 A-C:

Figure 5 A-C: Filter Release, Illustrated

FIGURE 5 A
FIGURE 5 A-1

FIGURE 5 B
FIGURE 5 B-1

FIGURE 5 C
FIGURE 5 C-1

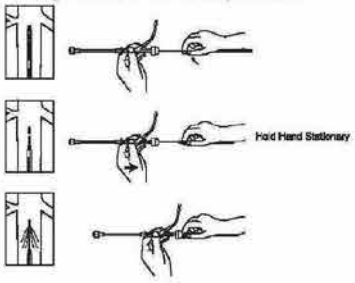


Figure 5 A: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.
Figure 5 A-1: Filter positioned at the distal end of the introducer sheath, with the filter retrieval hook, proximal to the introducer radiopaque tip.

PRECAUTION: Do not deliver the filter by pushing it beyond the end of the introducer sheath. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer sheath as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter retrieval hook 1 cm below the lowest renal vein.
Figure 5 B: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.
Figure 5 B-1: Unsheathing of filter in IVC.
Figure 5 C: The position of the hands at the completion of the unsheathing process.
Figure 5 C-1: The filter deployed in the IVC.

16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer sheath assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer sheath patency.

Follow-up Venacavogram

18. A follow-up venacavogram may be performed after withdrawing the introducer sheath into the iliac vein (typically 30mL of contrast medium at 15mL/s).
19. Remove the introducer sheath and apply routine compression over the puncture site in the usual way to achieve hemostasis.

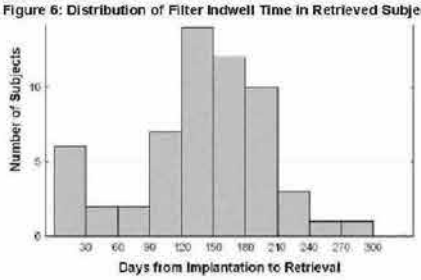
OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the *G2*® Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6 . The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure 6 depicting the time to retrieval.

Figure 6: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the ***Recovery Cone***® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.
There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.
Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Removal of *G2® X* Filter Using an Intravascular Snare

Equipment Required

- One intravascular snare of user's choice
- One 80-cm introducer sheath, 7F ID or greater, to be used as retrieval sheath
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Procedural Instructions

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Remove the retrieval sheath from its packaging using sterile technique.
3. Prior to use, flush the retrieval sheath with heparinized saline or suitable isotonic solution.
4. Prepare all other procedure components according to the manufacturers' Instructions for Use.
5. Use appropriate technique to determine that the filter, the jugular retrieval route, and distal IVC are free of thrombus.
6. Select the appropriate loop diameter size of the intravascular snare.
7. Assemble the intravascular snare according to the Instructions for Use provided by its manufacturer.
8. Insert the guidewire of choice into the retrieval sheath using the guidewire tip-straightener. Gently advance the guidewire into the IVC under fluoroscopic guidance such that it is caudal to the filter.
9. Introduce and advance the tip of the retrieval sheath such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.
10. Remove the guidewire.
11. Insert and advance the intravascular snare assembly through the sheath until it protrudes out of the sheath such that the marker band of the snare catheter is cephalad to the filter retrieval hook.
12. The retrieval of the ***G2® X*** Filter using an intravascular snare is illustrated in Figure 7 A-E:

Figure 7 A-E: Retrieval of *G2® X* Filter using an Intravascular Snare, Illustrated

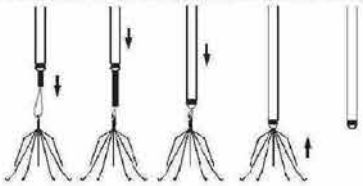


Figure 7 A: Slowly advance the loop forward over the filter apex.
Figure 7 B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until the loop engages the filter retrieval hook.

NOTE: Ensure that the loop of the snare has properly engaged the retrieval hook and that the retrieval hook, retrieval catheter and snare are aligned. Be careful to snare the apex of the hook; not the side. The marker tip of the snare catheter must be cephalad to the filter retrieval hook.

NOTE: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

Figure 7 C: Advance the sheath in the caudal direction until it aligns with the distal tip of the snare catheter.
Figure 7 D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the retrieval sheath by retracting the intravascular snare.
Figure 7 E: Continue retracting the snare until the filter is completely collapsed inside the sheath. Once the filter is fully collapsed inside the sheath, retract the complete system as a unit out through the sheath.

WARNING: Do not attempt to remove the *G2® X* Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.

WARNING: Remove the *G2® X* Filter using an intravascular snare or the *Recovery Cone®* Removal System only.

13. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

14. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
15. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Removal of *G2® X* Filter Using *Recovery Cone®* Removal System

Equipment Required

- One ***Recovery Cone®*** Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with ***Recovery Cone®*** Removal System and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

If the physician chooses to use the ***Recovery Cone®*** Removal System to remove the ***G2® X*** Filter, it is available from C. R. Bard, Inc.

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone®*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the ***G2® X*** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein, such that the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the ***G2® X*** Filter.

***Recovery Cone®* Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone®*** Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline-preferably heparinized saline.
13. Loosen the Toughy-Borst and slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the sidearm open and directly to the introducer catheter. The introducer catheter and the retrieval cone system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.
17. The retrieval of the ***G2® X*** Filter using a ***Recovery Cone®*** Removal System is illustrated in Figure 8 A-E:

Figure 8 A-E: Retrieval of *G2® X* Filter using *Recovery Cone®* Removal System, Illustrated

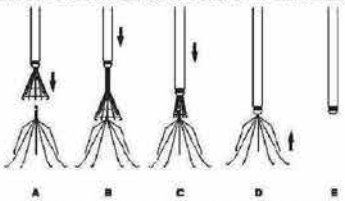


Figure 8 A: After the cone has been opened superior to the filter, carefully advance the cone over the retrieval hook by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the retrieval hook.
Figure 8 B: Close the cone over the retrieval hook by advancing the introducer catheter over the cone while holding the pusher shaft stationary.
Figure 8 C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.
Figure 8 D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.
Figure 8 E: The filter has been retracted into the catheter.

WARNING: Do not attempt to remove the *G2® X* Filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook is embedded within the vena cava wall.

WARNING: Remove the *G2® X* Filter using an intravascular snare or the *Recovery Cone®* Removal System only.

NOTE: It is recommended to fluoroscopically image the filter in AP and lateral views during retrieval.

NOTE: If difficulty is encountered while attempting to engage the retrieval hook and/or multiple passes are required, consider using an intravascular snare as an alternate retrieval method.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the ***G2® X*** Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the ***G2® X*** Filter retrieval hook, one may use a guidewire to facilitate advancement of cone over the retrieval hook.
Withdraw the introducer catheter and cone shaft away from the retrieval hook. Insert a 0.035" 260 cm guidewire through the central lumen (a stiff guidewire with J or angled tip is recommended).
Advance the guidewire through the cone and through the filter near the retrieval hook.
After it has been confirmed that the guidewire is in contact with or in close proximity to the retrieval hook, advance the cone over the guidewire to the retrieval hook.
Advance the introducer catheter to slightly collapse the cone over the retrieval hook. Withdraw the guidewire into the pusher shaft. Continue removing the Filter as described in step 17.

J. How Supplied

Each ***G2® X*** Filter is supplied preloaded in a storage tube. Each ***G2® X*** Vena Cava Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

WARNING: After use, the *G2® X* Vena Cava Filter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The ***G2® X*** Vena Cava filter should be stored in a cool (room temperature), dark, dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter After Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hagspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.

G2 X Filter

G2 X Filter Femoral Delivery Device

G2 X Filter Introducer Sheath With Dilator

FEM Femoral

Use By

LOT Lot Number

REF Catalog Number

Attention, See Instructions for Use

STERILE EO Sterilized By Using Ethylene Oxide

NON PYROGENIC Non-pyrogenic

Keep Dry

Keep Away From Sunlight

Single Use

Do Not Resterilize

Do Not Use If Package Is Damaged Or Opened

MR Conditional

INT (1) 7 Fr. Introducer Sheath 48cm Long with Dilator

KIT (1) G2 X Filter - Femoral Delivery Device
(1) 7 Fr. Introducer Sheath 48cm Long with Dilator

DD (1) G2 X Filter - Femoral Delivery Device

SET (2) 7 Fr. Introducer Sheath 48cm Long with Dilator

Recommended Guidewire

Manufacturer:

Manufacturer:
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA

TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardpv.com

BARD
PERIPHERAL
VASCULAR

PK5100095 Rev. 0 03/09

Exhibit J-H

G2® Filter System

Timeless Performance®

G2® Filter System

Femoral Vein Approach

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The *G2®* Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the *G2®* Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheathe and release the filter and allow it to recover to its predetermined shape. The centering system allows the *G2®* Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing.

The *G2®* Filter is designed to act as a permanent filter. When clinically indicated, the *G2®* Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The *G2®* Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRI Safety:

Non-clinical testing has demonstrated that the *G2®* Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less;
2. Spatial gradient field of 450 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the *G2®* Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner.

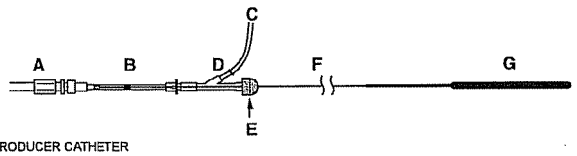
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the *G2®* Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

B. Device Description

The *G2®* Filter System - Femoral consists of the filter and delivery system. The *G2®* Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The *G2®* Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The *G2®* Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the *G2®* Filter, a storage tube with saline infusion port, and a pusher system. The *G2®* Filter is packaged pre-loaded within the delivery storage tube.

Figure A. *G2®* Filter System - Femoral



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the *G2®* Filter

C. Indications for Use

The *G2®* Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- *G2®* Filter may be removed according to the instructions supplied under Section labeled: Optional Procedure for Filter Removal.

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

D. Contraindications for Use

The *G2®* Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

***G2®* Filter Implantation**

1. **The *G2®* Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the *G2®* Filter cannot be safely reloaded into the storage tube.**
2. **Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)**
3. **Delivery of the *G2®* Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.**
4. **The *G2®* Filter System - Femoral is designed for femoral approaches only. Never use the *G2®* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *G2®* Filter orientation within the IVC.**
5. **If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.**
6. **Only use the *Recovery Cone®* Removal System to remove the *G2®* Filter. Never re-deploy a removed filter.**
7. **Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.**
8. **Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.**
9. **Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.**
10. **Persons with allergic reactions to nickel may suffer an allergic response to this implant.**
11. **After use, the *G2®* Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.**

See Potential Complications section for further information regarding other known filter complications.

***G2®* Filter Removal**

1. **Do not attempt to remove the *G2®* Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena cava wall.**

   NOTE: It is possible that complications such as those described in the "Warnings", "Precautions", or "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. **Use only the Bard *Recovery Cone®* Removal System (packaged separately) to retrieve the *G2®* Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.**
3. **Never re-deploy a removed filter.**

F. Precautions

***G2®* Filter Implantation**

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. This device has neither been studied in pregnant women, nor in suprarenal placement position.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter. Retrieve the *G2®* Filter using a *Recovery Cone®* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
11. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
12. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
13. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

***G2®* Filter Removal**

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone®* Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the *G2®* Filter with the *Recovery Cone®* Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter.
3. Remove the *G2®* Filter using the *Recovery® Cone* Removal System Only. (Reference Optional Procedure for Filter Removal for specific removal instructions).
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device

See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Deep vein thrombosis
- Caval thrombosis/occlusion
- Extravasation of contrast material at time of venacavogram.
- Air embolism
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization
- Infection
- Intimal tear
- Stenosis at implant site.
- Failure of filter expansion/incomplete expansion.
- Insertion site thrombosis
- Filter malposition
- Vessel injury
- Arteriovenous fistula
- Back or abdominal pain
- Filter Tilt
- Hemothorax
- Organ injury
- Phlegmasia cerulea dolens
- Pneumothorax
- Postphlebitic syndrome
- Stroke
- Thrombophlebitis
- Venous Ulceration
- Blood Loss
- Guidewire entrapment
- Pain

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use:

- One *G2®* filter and Delivery System that contains:
  - One 48cm, 7 French I.D. introducer catheter and dilator set
  - One Storage tube with pre-loaded *G2®* Filter and pusher delivery system
- 0.038" 3mm J-tipped Guidewire, 110cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: Scalpel, #11 blade, local anesthesia, drapes, etc

If the physician chooses to percutaneously remove the *G2®* Filter, the *Recovery Cone®* Removal System is available from C.R. Bard, Inc.

I. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

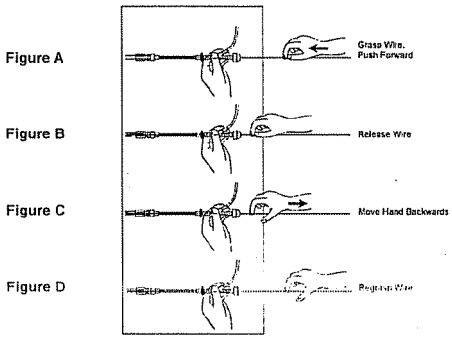
Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

11. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
12. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.

Advancement of G2® Filter, Illustrated



13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

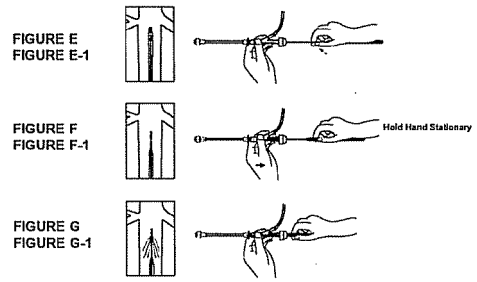
Filter Release/Deployment

14. Deliver and release filter as described below:

Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.

Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheathe the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tub assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

15. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Vencavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30mL of contrast medium at 15mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the *G2®* Filter using the *Recovery Cone®* only.

Removal of *G2®* Filter

Equipment Required

The following equipment is required for use:

- One *Recovery Cone®* Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with *Recovery Cone®* and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium

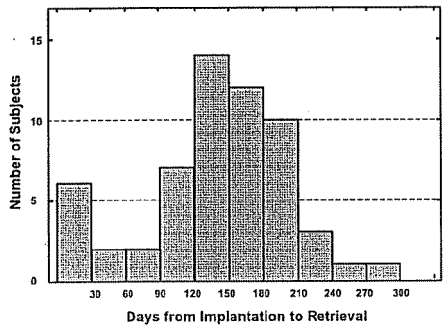
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the ***G2®*** Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time to retrieval.

Figure H: Distribution of Filter Indwell Time in Retrieved Subjects



Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the ***Recovery Cone®*** Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone®*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the ***G2®*** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the ***G2®*** Filter.

Recovery Cone® **Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone®*** Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

G2® Filter Removal, Illustrated

17. The capture of the G2® Filter is illustrated in Figures A-E:

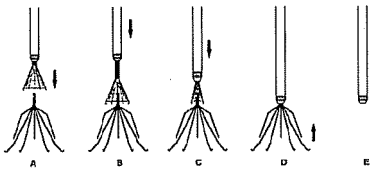


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter.

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the G2® Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the G2® Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip.

Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 17.

J. How Supplied

Each ***G2®*** Filter is supplied preloaded in a storage tube. Each ***G2®*** Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Warning: After use, the G2® Filter Delivery System and accessories may be a potential biohazard. **Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.**

The ***G2®*** Filter should be stored in a cool (room temperature), dry place.

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

For additional vena cava filter clinical information please refer to the following societal guidelines:

- **"Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [ACR Practice Guideline 2007; 38:673-684]**
- **"American College of Chest Physicians: Opinions regarding the diagnosis and management of venous thromboembolic disease. ACCP Consensus Committee on Pulmonary Embolism. American College of Chest Physicians" [Chest 1998 Feb; 113(2): 499-504]**
- **"Practice Management Guidelines for the Prevention of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group" [J Trauma 2002; 53:142-614]**
- **"Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" [JVIR 2003; 14:S271-S275]**

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.: Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hagspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters: Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.


G2® Filter System

Femoral

Femoral Introducer Catheter

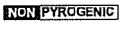

Use By

Lot Number

REF Catalog Number


Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide



Non-pyrogenic


Single Use.


Do Not Resterilize.


Do Not Use If Package Is Damaged Or Opened.

MR Conditional


Contents: Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System


Protect From Heat


Keep Dry


Recommended Guidewire


Manufacturer:

Bard, *G2®*, *Recovery Cone®* and Timeless Performance are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.


Manufacturer:
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA

TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardpv.com

BARD PERIPHERAL VASCULAR

PK5250500 Rev. 1 07/09

Exhibit J-N

From: Schulz, Gin [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=GSCHULZ]
Date: 12/19/2005 6:34:08 PM
To: Shifrin, Kevin [Kevin.Shifrin@crbard.com], Hudnall, Janet [Janet.Hudnall@crbard.com]
Subject: FW: Recovery Filter Limb Fractures
Attachments: RF Limb detch 1206051a.doc

Kevin and Janet,

Chris had asked Rich to pull together an addendum to the November 2004 R002. Cindi Walcott, Len, Shari and I spoke with Dr. Ciavarella Friday. The overall reported rate of fractures is now estimated to be 0.3% (was 0.16%) and the reported rate of fractures judged to be serious (Critical R002 rating) has gone from 0.046% to 0.13%(Critical/serious being defined by Dr. Ciavarella last year as those involving migration to heart or lungs or other critical organs).

Cindi mentioned that 3 of these 89 separate reports involved a single filter in a single patient. The scenario could have been multiple updates on the same case, e.g. a fracture was reported and then re-reported after it migrated. This stuttering reporting may be an aberration. Cindi is reviewing all 89 (now 90, see below) events to be sure that the event rates are calculated based on number of filter (same as number of patients probably) rather than number of fractures. That what she is referring to below.

Since the frequency of Critical events was now in the R002 Occasional range, we need to reassemble the BPV PAT to discuss the new information. How can I get a good estimate of the number of RNFs still implanted? That number is important to gauge residual risk. Also, do you have a good estimate of the number of RNFs not implanted, but in inventory?

Thanks for your help.

Gin

From: Walcott, Cindi
Sent: Friday, December 16, 2005 3:24 PM
To: Ciavarella, David; Schulz, Gin; Allen, Shari; DeCant, Len
Subject: Recovery Filter Limb Fractures

To All,

Attached is the data involving the Recovery Filter limb fractures as we discussed it during today's conference call.

Each of the 89 events will be further reviewed to determine how many patients were involved in these complaints.

Please note that while we were on the conference call, Field Assurance received a phone call with new information on one of the newer events that had not been classified on the attached report as a serious injury. The new information indicated that a filter arm had migrated to the heart, and perforated the heart and the pulmonary artery. This would change the number from 39 to 40 for reported serious injuries. The patient indicated he was pursuing litigation. Therefore, this e-mail and the attachment should be considered confidential information.

Cindi

Exhibit J-O

Deposition of:

Thomas Kinney , M.D.

June 17, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
800.808.4958 | calendar-atl@veritext.com | 770.343.9696

Q. Okay. How about post-market adverse event tracking?

A. I think I can understand that. I don't -- I am not an expert. No one would say -- no one would look in the Yellow Pages, if people still do that, and say, you know, that's for the expert Dr. Kinney under there. But basically, the analysis that a physician does or an engineer does, I think you can -- I think you can have some insight there.

Q. But other than this lawsuit, you don't have any education, training, or experience in post-market adverse event tracking?

MR. JOHNSON: Form objection.

Also vague and overbroad.

BY MR. BROWN:

Q. Is that fair?

A. No specific training, no.

Q. Do you consider yourself an expert in what might constitute a safety signal for a medical device?

MR. LOPEZ: Form.

THE WITNESS: I wouldn't say I'm an expert, but I'm a physician. So we do procedures on people, and we get signals all the time about what's working and what's not working; and if we don't listen to those signals, people get hurt very bad sometimes and including

Q. I don't know. You said it. That's why I wanted to ask you about it.

A. They said they were going to do a study.

Q. Do you remember who told you that they were going to do a study?

A. I remember Janet Hudnall saying that. I don't know if Rob Carr said it also. I don't remember.

Q. Did Janet Hudnall and Rob Carr tell you that they were going to do -- not they -- that Bard was going to do a long-term study of the Recovery filter?

A. Yes.

Q. Do you remember when that occurred?

A. It would have been between 2004 and probably 2005 or '6. I think it was about the time we were doing those animal evaluations to come up with a G2.

Q. Do you have any idea about the specifics of the study that they were telling you was going to be performed?

A. There wasn't no specifics, but there was -- it was going to be a long-term evaluation.

Q. Do you have any knowledge about what happened at Bard as far as that long-term study of the Recovery filter?

A. Not specifically. But it seems like they ended up -- you know, it kind of evolved into like the Everest

study, which is really just -- again, it became a short-term retrieval study for the G2, which to me, when I review that, there were some signals in even that short-term study that again begged the question that we really need a long-term study to have factual data that we could really talk to patients about the risk and benefits of the Bard -- the new generation Bard filter.

I mean, it was -- it was labeled to us as this was the only filter we were going to need. It had, you know, you know, unsurpassed fracture resistance and positional stability. And, you know, we hear those things, and we believe those things, and then you start finding out that that's not true and, you know, it kind of voids -- voids all the honesty and transparency things that are so important when we talk to patients about consent and trying to tell a patient about what that particular complication means for them, and why they are -- they are subjected to that or the anxiety of that, all that stuff.

Q. You mentioned the Everest study, which was a six-month study for the G2 filters; is that right?

MR. JOHNSON: Form.

THE WITNESS: Correct.

BY MR. BROWN:

Q. And then you said that you envisioned that there would be a long-term study; right?

consent to their patients."

Do you see that?

A. I do.

Q. Is it your opinion that physicians should receive all bench testing for medical devices that they use?

MR. JOHNSON: Form.

THE WITNESS: Most -- Most physicians don't. They don't want to know bench testing, but they do want to know when the -- you know, that there's data that shows that a company has been tracking data that shows statistically that it had higher rates of perforations, migrations, fractures, and they are not notified.

BY MR. BROWN:

Q. Okay. We'll get to that in a second, but I just want to focus on everything that you're saying --

A. Okay.

Q. -- that physicians should receive.

So as far as the bench testing, you're not saying that physicians should receive all bench testing?

MR. JOHNSON: Just note my objection. The question has been asked and answered. Paragraph 8 doesn't even mention bench testing, so I don't understand the question.

BY MR. BROWN:

Q. Do you understand the question, Doctor?

A. Yeah, it's asking about performance. So performance to me is the important clinical parameters, like recurrent pulmonary embolism, issues about perforations, migrations, fractures, those are recurrent -- DVT, caval thrombosis. I think those are performance issues that physicians would want to know. For instance, if they had trouble deploying the filter, I think it's probably important for physicians to know.

I don't -- They are not going to want to know, you know, migration tests or pole tests. I might be interested because I'm a strange person, I suppose, but I think most clinicians would not want to know.

Q. So what you're referring to in Subparagraph A relates to the clinical information? In other words, the adverse events that are actually occurring in people; is that right?

MR. JOHNSON: Objection. Form.

THE WITNESS: Yeah, yeah. I mean, this gets gray for me because suppose there's animal models that you think are good animal models, and they show issues, that becomes maybe important. That may become important. But I think as a general, what you are saying is true, but --

BY MR. BROWN:

Q. Do you think that physicians would want to know

the animal model testing related to the Bard filters?

A. Well, if --

MR. JOHNSON: Form.

THE WITNESS: If it showed -- If there were issues that occurred with that, you know, I would think physicians might be interested in that.

BY MR. BROWN:

Q. But you're not offering that opinion in this case, are you?

A. You know, see, it's hard for me because I have looked at the data in the Kessler study, and I just -- I'm amazed what they decided to do for parameters to assess this filter. I mean, they -- they basically had flawed studies to get through an FDA safety and equivalency for Simon Nitinol, which I think were -- maybe some of the fault is FDA, but I think -- I think if I was aware of those as, you know, in my role with Bard kind of trying to introduce patients -- not patients, but physicians to put this filter in, I think if I had known about that, I would have said, "I'm not really so sure I'm comfortable about this." Especially in light of the way things have turned out where they have shown statistically high rates of -- of migration, perforation, fractures. So I don't know. I might be off the track a little bit, Matthew, but am I -- am I getting my message across?

Q. Is it your opinion in this case that medical device companies should provide all complaint files for the medical devices to physicians?

MR. JOHNSON: Form.

THE WITNESS: You know, I would say as a general statement, no. But when you -- when you start getting to see signals, I think that's of concern because it's transparency, and it's our ability to really do an adequate informed consent. You know, that's -- or even device selection for us. So I was -- You know, I thought I was in a unique position with Bard; that, you know, I was kind of a consultant with them. I helped them do animal studies to get approval of what I thought were better devices. They never showed me the data of any of the animal studies I did. And then furthermore, they never showed me any of this data that maybe would have been -- I might have had opinions about that might have been helpful for them. And you go why is that? Why -- Why was my opinion not important? And maybe if I had the chance to look at that data I would have said, "I'm not so sure about this test. You know, maybe we need to do more."

You may get to this later, but, you know, they talked to us in 2006 with this consensus agreement, and then they -- they met with me a little bit after that asking

of the requisite preclinical and clinical safety and effectiveness/risk benefit evidence that is mandatory to justify widespread marketing of IVC filters for both temporary and permanent placements."

Do you see that?

A. Yes, I do.

Q. All right. What is the standard that you're using to define physicians' reasonable expectations?

A. You know, I think this has to do with basically really knowing the long-term performance characteristics of the filters that were -- we're putting in and also -- and so that includes the effectiveness, say, clot-trapping ability and includes what those risks are, such as what we have mentioned. These fractures, embolizations, the migrations. So that's -- I think physicians want to know. They are expecting to know that.

Really to do proper trans- -- transparent consent and actually for selection also, selection of devices, you know, you want to do the best thing for your patient, so you want to know which device is the safest and the most effective and which has -- has a reasonable risk-benefit ratio. So I think to have physicians try to decide this without that data is kind of -- it's marketing basically, or it's kind of like the filter is the best filter since -- This is the only filter you'll ever need. You

are kind of like well, that's kind of nice, but that doesn't really help me select, say, your filter versus somebody else's filter.

Q. Is Paragraph B suggesting that physicians should receive all preclinical safety and effectiveness evidence --

A. No.

MR. JOHNSON: Form.

BY MR. BROWN:

Q. -- for IVC filters?

MR. JOHNSON: Go ahead.

THE WITNESS: It's -- It's the pertinent -- the pertinent stuff which we have been talking about, you know. But not -- I'm sure your world is an overwhelming amount of information. Our world is no different than your world. So -- But we want to know the things that help us make decisions, clinical decisions, and those are recurrent pulmonary embolism, yeah, we want to know about that. We want to know about caval thrombosis. We want to know about recurrent DVT. We want to know about fractures, embolizations, migrations, difficulties putting filters in. I think those are -- those are the things that are important to us.

BY MR. BROWN:

Q. So information that the company has related to

system, and we don't know -- we don't know what type of filter it is, I'll do a KUB or a CT scan to see if that's a difficult undertaking for me.

But maybe that's a little different than this because what we're talking about here, we're talking about a series of different devices that has, you know, higher than our normal rates of fractures, migrations, embolizations, perforations. And so how do we -- how do we figure those out? How do we guide our patients as to what's the right thing to do and are they at risk? And so that's -- that's what this is.

Q. What are you saying that Bard should have provided as it relates to this paragraph?

A. Well, you know, this is -- First of all, we should have been notified about, you know, their concerns about these high rates of issues. And then if you're convinced that these are issues that are going on, how do you figure out what patients are at risk from some potentially life-threatening complication?

Q. Would the answer be some type of imaging?

A. Imaging is one, one thing. I mean, we do a clinical evaluation, and imaging helps us. I mean, clinical is only so good. You can't really feel a filter, so the imaging does help you.

Q. Paragraph 75 reads, "It is our opinion that Bard

lacked important safety information when it began marketing each of their IVC filters regarding the risk of complications associated with their IVC filters and, once on the market, failed to provide practicing physicians with timely and updated information of these risks, including, without limitation, adequate information related to the character, severity and frequency the Recovery, G2/G2X and Eclipse IVC filter's high complication rate in relation to its competitors and its own products, including the SNF filter. This lack of information precluded physicians from evaluating the risk-benefit analysis for their patients. If Bard had disclosed the information discussed within this" -- "within this report, reasonable physicians would not have used these devices."

A. Okay.

Q. Does this paragraph relate to what we were discussing earlier concerning what you believe Bard should have told physicians about -- physicians about complication rates associated with the filters?

MR. JOHNSON: Form.

THE WITNESS: I would say, yeah, in a general sense, I would say that's true.

BY MR. BROWN:

Q. Is there anything else that you think Bard

Exhibit J-P

Deposition of:

Anne Roberts , M.D.

July 7, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
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Dr. Anne Christine Roberts, M.D. This deposition is being held at 4240 La Jolla Village Drive, San Diego, California 92037.

Videographer is Scott Tanaka here on behalf of Veritext Legal Solutions. Today's date is July 7th, 2017. Back on the record. The time is 4:02 p.m.

BY MR. BROWN:

Q Dr. Roberts, you all right?

A No. Fine.

Q I want to go through some of your report with you. Okay?

A Okay.

Q So if you have it in front of you, we can flip through it together.

A I do.

Q The first thing is I wanted to ask you about paragraph 3 --

A Sorry. What page?

Q Page 6.

A Paragraph 3. Okay.

Q It says, We have been asked to provide our expert analyses and opinions on the following. Then "A" says, four lines down, Considering patient safety is the primary concern and that

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open, honest, and complete performance, safety and complaint data from manufacturers are required for physicians to fulfill their standard of care responsibility to provide informed consent to their patients.

Do you see that?

A I do.

Q Have you ever had an IVC filter manufacturer provide you with the complete performance, safety and complaint data regarding their IVC filters?

A This is probably the thing that makes me the craziest about this suit at all is the fact that Bard knew that there was a problem and even -- now granted, did I know? No. Because nobody told us. It wasn't out there. It was something that was known by Bard internally. They had been looking at this. They knew there was a problem.

And if you go back to even their health analysis, hazard analysis even -- as you know, in December of 2004 they basically -- they basically talk about the fact that there's a problem with this device. And, you know -- and that, you know, they see in the MAUDE database that the reporting

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rates were 4.6, 4.4, 4.1, and 5.3 times higher than reporting rates of all other filters.

This is the health hazard analysis by David Ciavarella. Anyway, you know, and he looked at this -- and this is in December -- December of 2004. And nobody came back and said, Wow, we're really having a problem. Now, I don't -- you know -- I mean, I think that physicians should have known about this at that time.

So that basically -- but even more importantly, Bard should have stopped selling these things and said look, you know, we've got a problem here. We need to figure out what it is that's going on with this filter. And nobody -- nobody does that. And it's basically hidden. Nobody tells anything.

So it's not until these other memos come out where somebody else does their own, you know, hazard analysis and says, you know, we got a problem here that all of a sudden the community starts to understand that there is a problem here. So it's not -- you know, I mean -- this is the thing that really, really bothers me about this whole thing is the fact that -- I mean, I look at this as a physician. I'm taking care of patients.

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I'm responsibile for telling patients if I'm going to put in a filter that at least I know what it is that's going on.

And, in fact -- in fact, I can't give a patient true consent because I -- I didn't have the faintest idea that this is what was happening with this filter. And Bard was not at all transparent about this. And they should have been. They should have come -- they should have either stopped selling it and said, look, you know, we're going to -- you know, we've had some problems with this. We're going to, you know, redesign it. We're going to redo our bench top testing. We're going to show that -- you know, we're going to make sure it's okay. Then we'll see about rereleasing it.

But they didn't do that. And I think that that's the thing that's so bothersome about this case is basically, you know, people covered it up. People hid it. They didn't allow the physicians to know about it. They didn't -- there was no way to consent the patients appropriately. And, quite frankly, I think at least at this point in time people -- because they assumed that it was -- it was a filter that, yeah, it was supposed

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to be retrievable but it also had a permanent indication that it could stay in permanently and wouldn't cause problems.

And I think the -- this is where -- this is where it all falls apart. This exactly -- patient safety. You know, any manufacturer should put patients' safety as the most important thing in selling something. You can't in good faith sell something that isn't safe. It's supposed to be -- you know, it's one of the things Kessler says in his report. It's supposed to be as safe and effective as the predicate device. And if the manufacturer realizes it's not as safe, they should not be selling it. Okay? So yeah. That's my problem with this.

Q So in your opinion the information that's contained in that health hazard evaluation by David Ciavarella in December of 2004 should have been provided to physicians?

MR. JOHNSON: Form objection.

BY MR. BROWN:

Q Is that what you're saying?

MR. LOPEZ: Only that after five minutes?

MR. BROWN: That's not what I'm asking.

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BY MR. BROWN:

Q I'm asking you if it's your opinion that the information that's contained in that health hazard information from December of 2004 should have been provided to physicians.

MR. JOHNSON: Form.

THE WITNESS: I think, first of all, yes, it should have been provided to physicians that we have a problem. Okay? Mission control, we got a problem. Let's -- and then I think on top of that Bard should have said we have a problem. We are putting patients at risk. This is not the predicator device. This is not other filters that we've seen before. And we need to stop this, and we need to look at the data. We need to see what it is that's causing this problem.

And that's -- yes, I think they should have told physicians. And I think -- I'm not saying you take this memo and you give them a memo. But you tell them we have a problem. And, more importantly, you stop putting it out there until you figure out what the problem is. Okay?

I'll give you an example. When Meditech put out the redesign -- put out the titanium

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filter, they put it out -- they had done some testing on it. Looked like everything was okay. They put it out in a relatively small release. They put -- I mean, for example, we put them in -- we were big Greenfield user. They wanted us to put them in -- they knew we knew how to do it, blah-blah-blah.

So we start putting them in. We start seeing that these things migrate. So, yes, filters -- the legs can perforate and can -- they didn't migrate the filter itself. It slid down a little bit because the leg perforated. But we called them and said we've got a problem. There's a problem with this patient. They stopped -- they stopped it. They stopped selling them. They stopped sending them out. They called back the ones that they had and said we got to figure out what the problem is. And they redesigned it, and then they put in another one.

That's what Bard should have done. Bard should have said -- they got these memos. They should have looked at this and went to the QA person and said we've got a problem here. Nothing happened. Just let's go ahead keep selling them, keep selling them, keep selling them, you know,

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until tens of thousands of these things were sold and put into people, at least, presumably, most of them.

You know, maybe some that got expired didn't get put in, whatever. But a lot of them got sold. And this is -- you know, this is -- for me this is the major concern that I have.

When I started seeing this stuff, this is when I said I'm willing to testify because this to me goes to the heart of the issue which is I don't care if it's a manufacturer, you know, what it is. You got to be honest. You got to tell people. You can't cover it up. You got to tell your physicians. The physicians have to know so they can make a decision. Do we still put this thing in? If they don't know that this is a problem that Bard knows about and they don't disclose it to the physician, what's the physician supposed to know?

They're waiting to hear, you know, memos from Temple or waiting to hear, you know, something to get published. And in the meantime it's just getting put in patients. And that's the scary thing about this.

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BY MR. BROWN:
Q Do you know?
MR. JOHNSON: Form.
BY MR. BROWN:
Q Do you know what the regulations are?
MR. LOPEZ: Different question. Hold on. He asked you two questions.
MR. BROWN: No, I didn't.
MR. LOPEZ: Yeah, you did. You said regulations.
MR. BROWN: That's what I said in my first question. I said do you have any knowledge about the regulations that govern the kind of information the medical device companies are permitted to share with physicians?
BY MR. BROWN:
Q Do you have any knowledge of the regulations?
A A device company can share --
Q That's not my question.
A I'm just saying --
Q I'm asking you a question. Please answer my question.
Do you have any knowledge of the regulations about the type of information that a

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medical device company is permitted to share with physicians?
MR. JOHNSON: Form objection.
Explain yourself if you have to.
THE WITNESS: I don't believe that there are regulations that prohibit device companies from sharing information. Now, that is not necessarily true with other regulatory agencies such as FDA which cannot share information -- proprietary information to the public or anybody else with -- you know, without the consent or not even with the consent of the company. The company should be under no restraint from sharing information if they deem it reasonable.
BY MR. BROWN:
Q Has any medical device company provided you with its testing and monitoring data for their patients?
MR. JOHNSON: Form.
THE WITNESS: Well, number -- I mean, in terms of -- for example, in instructions for use there can be information about patients and patient outcomes and specific information about patients. So to that extent, yes, I think companies do share that information partially

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probably because they're required to by the instructions for use. They will -- if there is a clinical trial, they -- that clinical trial data will be published. So that, I assume, is considered sharing of company information.
BY MR. BROWN:
Q In any other context has a medical device company provided you with its testing and monitoring data for their products?
A I don't know that I've actually asked them.
Q So, no, they have not?
A Outside of the context of clinical trials -- in a clinical trial, yeah, you get all of that data.
Q Anything else?
A Anything else?
Q Are there any other instances in which a medical device company has shared with you its testing and monitoring data other than in the IFU or the clinical trial data?
MR. JOHNSON: Form.
THE WITNESS: I don't believe so. I don't know that I've asked for it. And I don't know that anyone has come to me and said, here;

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this is our data.
BY MR. BROWN:
Q There are opinions that you've given in paragraphs 3, 4, 6, and 7. And take a minute to refresh your memory about what those opinions are.
A Okay.
Q Let me know what you have --
A Was it the one we've kind of gone through that has multiple subsections? Is that correct?
Q That's right.
A So we have covered those now?
Q So three, four, six, and seven.
A Four, four. Oh, not five. Okay.
Q All of those paragraphs concern your opinions about the type of information that Bard should be providing to physicians and to patients, correct?
A Yes.
Q Do you have any written standard or authority that you're relying on to make any of the opinions that are in those paragraphs?
MR. LOPEZ: Form.
THE WITNESS: I don't have any written standards for that. I think that this is

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something that physicians expect from companies. Now -- and, again, I don't think in here that we mean that you give us all of your databank. I don't think it means that we expect that you're going to tell us everything about a device. I think what it means is that if a company finds that there is a problem and that problem is such that it affects the safety and efficacy of a device, then a company has an obligation either to get that device off the market temporarily or permanently or to make sure that physicians know what it is that they're up against so that they can make good informed consent for their patients.

BY MR. BROWN:

Q All of the opinions that we just discussed and the ones you reviewed in paragraphs 3, 4, 6, and 7 there's no way to test your opinion, is there?

MR. JOHNSON: Form.

THE WITNESS: Only to ask a patient or a family or the patient died and find out whether or not they think it's reasonable to know that the physician should have known about this so that they could inform their patient appropriately.

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BY MR. BROWN:

Q Any other way that you know of to test your opinions?

A Ask you whether you think it's reasonable or not.

MR. LOPEZ: Or we'll just let a jury decide maybe.

BY MR. BROWN:

Q If you got 100 doctors in the room, there's no way to tell which ones would agree with you and which ones would disagree with you?

MR. JOHNSON: Form.

MR. LOPEZ: About?

BY MR. BROWN:

Q About the opinions contained in paragraphs 3, 4, 6, and 7.

A Would be an interesting exercise. Maybe someone could do that study and show people this data and say, Out of 100 people that are in this room, how many people think that it would have been reasonable that the company release this data to the physicians who are implanting this device and putting, essentially, their patients at risk?

Q The opinions --

A Maybe I'll do the study.

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Q The opinions that you set forth in paragraphs 3, 4, 6, and 7, you've never published anything on those opinions, have you?

MR. JOHNSON: Form.

THE WITNESS: That companies should give safety and effectiveness data?

BY MR. BROWN:

Q The types of data that you are discussing in those paragraphs.

A Well, we say that we need safety and effectiveness data that the companies possess from testing and monitoring their medical devices, particularly implantable devices, to allow physicians to provide full and fair balanced informed consent to patients whom these devices are prescribed and indicated. I have talked about safety and effectiveness and how that is important in device regulation and in, you know, device design. So I guess I have talked about it.

I don't know that I talked about it in the context of this particular device or particular devices. But that, I think, is a very common standard that physicians use in terms of deciding whether or not to put a particular device into a patient.

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And, remember, there is a choice. Okay? There's a choice of the device to use. So if somebody knows that there's a question about the safetyness and effectiveness of a device, then at least they can choose or they can help involve their patient in the choice of what device to use. And if they feel that this device has characteristics that mitigate the potential for harm, then they can make that choice. But without that information, they have no way of making that choice.

Q Throughout your report you cite to Dr. Kessler's report, Dr. Ritchie's report, and Dr. Betensky's report; is that right?

A Yes. Among others, yes.

Q Did you ever read the 2016 deposition of Drs. Kessler and Betensky?

A As I said earlier, I don't believe that I've read Kessler's deposition.

Q Have you read the previous deposition transcript of Dr. Ritchie?

A I think I have. Remind me who Ritchie is because it's been a while.

Q Ritchie testified numerous times over the past several years.

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bad outcome that the -- that litigation in terms of -- in terms of how consent was obtained or whatever is not -- is going to be a little different from person to person potentially.

And so it's not something in terms of what the clinical decision is with -- by the practitioner.

BY MR. BROWN:

Q How does this document relate to your opinions in this case?

A Well, I think it's -- I don't think it has to do with the -- with litigation per se. I think this has to do with what it is that one owes a patient in terms of making sure that the patient or representative or, when appropriate, the patient's family has the opportunity to understand the treatment or procedure the patient is to receive and its reasonable risk benefits and alternatives to have all questions answered and to fully consent to the treatment or procedure.

So if you don't have information that's available, you can't give the patient or the representative or the patient's family an opportunity to really understand the treatment or procedure because you can't tell them what their

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reasonable risks and benefits and alternatives are to that procedure.

So if you believe -- or if you were to know that a device had a problem with it, then -- and you don't know that, you cannot give them the reasonable risk and benefits of the procedure. So that's where -- that's where the problem with the -- you know, that we're outlining here is that the informed consent requires -- requires that.

Q These practice parameters that we've marked as Exhibit 15 to today's deposition deal with providing certain information to patients, correct?

A Yes -- this one specifically for informed consent.

Q You're saying that in order for you to provide informed consent, as discussed in these practice parameters, you need certain information from Bard, correct?

A Well, I need -- you know, it doesn't -- it's any -- any manufacturer that -- you're -- you're giving a consent based on the data based on what is known about the product.

MR. LOPEZ: I think we're at seven hours, by the way.

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MR. BROWN: We're not. We have nine minutes.

THE VIDEOGRAPHER: We are 6 hours, 53 minutes of record.

BY MR. BROWN:

Q You don't have any written authority that you're relying on to say that the type of information that you're demanding from Bard is needed to satisfy the informed consent standard of care, do you?

MR. JOHNSON: Form objection.

THE WITNESS: I'm saying that a patient that -- if a company knows that there's a problem with their device or their drugs or whatever it is, that they have a duty to make sure that a practitioner is aware of that; if they're going to continue to sell that device, that they need -- the physician needs to know so they can do an adequate informed consent.

BY MR. BROWN:

Q That's the Dr. Roberts' standard, correct?

MR. LOPEZ: Form.

THE WITNESS: Well, we'll have to get 100 people in a room and find out.

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BY MR. BROWN:

Q But as we sit here today, we haven't gotten 100 people in the room to find out, have we?

MR. JOHNSON: Form.

THE WITNESS: Well, I mean, at least in here it would indicate that a physician -- that the physician should -- that the physician is supposed to give the best information to the patient in terms of risk and benefits of the procedure. And if you don't know, you give what you know.

MR. BROWN: Thank you, Dr. Roberts. I don't have any further questions for you at this time.

EXAMINATION

BY MR. LOPEZ:

Q While we are on that document -- if you just look at your report, Doctor -- it's easier for me to do it that way. If you look at page 10 of your report, we're talking about the same guidelines that Mr. Brown was talking to you about.

Do you see that?